EVALUATING THE EFFECTIVENESS OF EMERGENCY NURSE PRACTITIONER SERVICE FOR RURAL PATIENTS PRESENTING WITH CHEST PAIN

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BACHELOR OF NURSING
MASTER OF NURSING SCIENCE

Submitted in fulfilment of the requirements for the degree of
Doctor of Philosophy

Institute of Health & Biomedical Innovation
School of Nursing
Faculty of Health
Queensland University of Technology
2016

Keywords

Cohort study, chest pain, emergency service, emergency nurse practitioner, health services research, nested cohort study, nurse practitioner, observational research, quality of care, rural emergency service, rural research culture, safety and quality, systematic review.

Abstract

Background and significance

Nurse practitioners are registered nurses who are educated to practice with expert knowledge, complex decision-making skills and with legislated extensions to practice that includes diagnostics, prescribing medication and referral to other health providers. The emergency nurse practitioner service (ENP) model, the single largest subspecialty nurse practitioner group in Australia, is an innovative service model that was introduced in response to imperatives to improve access and equity for emergency department patients who were experiencing excessive waiting times for management, diagnosis and discharge. The implementation of the emergency nurse practitioner service as one step in addressing rural health reform has the potential to directly impact on service outcomes and quality patient care. Universally, one of the most important indicators for health services is the measurement of the quality and safety of patient care. Despite increasing use of the rural emergency nurse practitioner service model, there is a paucity of evidence that is reported in the national and international literature regarding the safety and quality of the service.

Aims

The aim of this study was to utilise the Donabedian framework of safety and quality in health care to examine the ENP service model in provision of care in the rural environment and to evaluate the effectiveness of the service in the management of patients presenting with undifferentiated chest pain.

Methods

A multisite prospective longitudinal nested cohort study was conducted to compare the effectiveness of emergency nurse practitioner service to standard medical care in the management of patients presenting to three rural emergency departments in Queensland, Australia. The emergency nurse practitioner service model included the delivery and coordination of care in the diagnosis, investigation, therapeutic treatment (including prescribing of medications and technical interventions) and referral for patients with undifferentiated chest pain. The standard care model was similar but delivered and coordinated by a medical officer. The management of adult

patients presenting with chest pain was observed and compared for differences in the safety and quality of care. A nested cohort, patients with suspected or confirmed acute coronary syndrome were identified. The primary outcome measure was adherence to guidelines for the nested cohort. Secondary outcomes were measured for the study cohort including service indicators and patient-reported outcomes.

This research used a variety of methods to assess study outcomes including the use of routinely collected demographic and clinical data, medical record review and patient survey. Two tested and validated tools were used to develop a questionnaire that was completed by participants at the emergency department occasion-of-service. Follow-up questionnaires were posted to all study participants at 30-days after the initial emergency department presentation. The first tool used was a modified Ausprac patient outcomes scale that incorporated multiple validated and tested tools. The second tool used was the SF-12® survey to measure quality-of-life and functional status. The tool contains 12 items that are used to construct physical component summary (PCS) and the mental component summary (MCS) scores.

A self-administered questionnaire, using a component of the National Nurse Practitioner Survey was completed by the nurse practitioner in each participating emergency department at the commencement of the study. The tool included items related to barriers and facilitators to practice and the professional (years of experience) and psychosocial (perceived level of competence) characteristics of the nurse practitioner. These data were collected to establish the structural characteristics of the emergency nurse practitioner service.

Results

A total of 61 participants were recruited to the study cohort from the three participating sites. Of these, 41 participants were identified for inclusion in the nested cohort. Twenty-three (37.7%) participants were managed using the emergency nurse practitioner service model, whilst the remaining 38 (63.3%) were managed using the standard care model. There was a higher proportion of guideline adherence for high-risk patients and those with diagnosed acute coronary syndrome who were managed by the emergency nurse practitioner service model. Overall, adherence to the guidelines by clinicians in this study was good with clinicians achieving a minimum of 64% compliance with acute coronary syndrome guidelines. The emergency nurse

practitioner model achieved a higher proportion of agreement (91.7%) than the standard care model (82.8%) for diagnostic accuracy of electrocardiograph interpretation (Fisher's exact test = 0.52). There were no significant differences between the two groups in regards to the service indicators of waiting time and length-of-stay. Participants were 2.4 times more likely to have an unplanned representation within seven-days if managed by the standard service model (Fisher's exact test, p=0.289). No differences between the service models was found for patient-reported outcomes. The majority (88.5%) of participants were highly satisfied with the overall quality of care, which was sustained over time. At the follow-up evaluation, 93.2% of participants reported that they were highly satisfied with the overall quality of care. When adjusted for age and sex, there was no difference between predicted summary scores for the SF-12 between service models. Although the mean PCS score did not change significantly from baseline to follow-up, there was an increase of 1.47 in the mean MCS score. Whilst statistically significant (p=0.05), this increase was not clinically relevant and unlikely to represent the effect of service intervention. The mean summary scores for the SF-12 for our study cohort, when adjusted for age and sex, were comparable with other contemporary research for adults with heart disease or those patients with ACS.

Conclusion

Emergency nurse practitioner service effectiveness was comparable to that of standard medical care in the management of patients presenting to rural hospitals with undifferentiated chest pain. These findings provide a foundation for the beginning evaluation of rural emergency nurse practitioner service in the delivery of safe and effective care beyond the minor injury and illness setting. The Donabedian Structure-Process-Outcome framework provided invaluable guidance for this examination.

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List of Abbreviations

ACS	Acute coronary syndrome
ADP	Accelerated diagnostic protocol
AMI	Acute myocardial infarction
AIHW	Australian Institute of Health and Welfare
ATS	Australasian Triage Scale
ATSI	Aboriginal and Torres Strait Islander
DNW	Did-not-wait
ECG	Electrocardiogram
EDIS	Emergency Department Information System
ENP	Emergency nurse practitioner
ENPC	Emergency nurse practitioner candidate
ED	Emergency department
GP	General practitioner
LOS	Length-of-stay
LWBS	Left without being seen
MACE	Major adverse cardiac event
MaP-RED	Managing chest Pain in Rural Emergency Departments cohort study
MLP	Mid-level providers
NP	Nurse practitioner
PA	Physician assistant
QoL	Quality-of-life
RCT	Randomised control trial
SF12	12-item Short Form 12 Health Survey
SPO	*[Donabedian's]* Structure-Process-Outcome *[framework]*
STEMI	ST-elevation myocardial infarction
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

Publications related to the research

Roche, T., Gardner, G. & Lewis, P. (2014). Retrospective observational study of patients who present to Australian rural emergency departments with chest pain. *The Australian journal of rural health*, 22(5):229-234.

Roche, T., Gardner, G. & Lewis, P. (2015). Effectiveness of an emergency nurse practitioner service for adults presenting to rural hospitals with chest pain: protocol for a multicentre, longitudinal nested cohort study. *British Medical Journal Open,* **5**:e006997 doi:10.1136/bmjopen-2014-006997

Roche, T., Jennings, N., Clifford, S., O'Connell, J., Lutze, M., Gosden, E., … Gardner, G. (2016). Diagnostic accuracy of risk stratification tools for patients with chest pain in the rural emergency department: A systematic review. *Emergency medicine Australasia*. doi: 10.1111/1742-6723.12622

Roche, T., Gardner, G. & Jack, L. (2016) *The effectiveness of emergency nurse practitioner service in the management of patients presenting to rural hospitals with chest pain: a multisite prospective longitudinal nested cohort study*. Manuscript under peer review.

Roche, T., Gardner, G. & Jack, L. (2016) *Perils and pitfalls in conducting rural health services research: a biographical case study"*. Manuscript under peer review.

Conference papers and presentations

Roche, T. (2015). Effectiveness of an emergency nurse practitioner service for adults presenting to rural hospitals with chest pain: protocol for a multicentre, longitudinal nested cohort study. *ED NURSPRAC, 6th Annual Australian Emergency Nurse Practitioner Conference, Melbourne*. Oral & poster presentation.

Statement of Original Authorship

The work contained in this thesis has not been previously submitted to meet requirements for an award at this or any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

Signature: QUT Verified Signature _____

Date: 15 September 2016

Acknowledgements

After all this time, today is the day; writing this note of thanks is the final act for my thesis. I would like to use this opportunity to reflect on the people who have supported and encouraged me so much during my studies.

First and foremost, my sincere thanks go to the patients who participated in this research and my colleagues who assisted me with my research project. Without their support and participation this research would not have been possible.

I also need to express my sincere gratitude to my principal supervisor Professor Glenn Gardner for her continuous support of my PhD studies and for her patience, motivation and immense knowledge. I could not have imagined a better advisor and mentor for my PhD. I remember the first day I met you and thinking that I wanted to grow up just like you!

Besides the Prof, I would like to thank the rest of my supervisory team: initially Dr Peter Lewis and later Dr Leanne Jack, for their insightful comments and encouragement.

I would also like to acknowledge my Australian Postgraduate Award scholarship for provision of financial support throughout my PhD.

To my wonderful "PhD family", Tash, Marg, Jane, Leanne and my ring-ins Stu and Matt, I would like to thank you for your wonderful collaboration. You inspired me greatly and were always willing to help when needed. We were not only able to support each other by deliberating over the research "blues", but also happily by talking about things other than just our research.

My sincere thanks go to my colleagues who assisted me with my research project. Without their support this research would not have been possible.

Thank you to all my friends who have put up with me being antisocial in my research endeavours. Thanks for your kind words and support during my PhD studies.

A special thank you to my good friend Fionna for her wise counsel and sympathetic ear. All the Asian chicken salad, coffee, chats, exercise and even "fresh air" made me feel loved!

Last but not least, I wish to acknowledge the unfailing support of my family, especially my long suffering husband, Con. His coffee making skills, along with his unfailing belief in me, has been an enormous support during my studies. To my children Jake, Charlie, Ben and Sophie, thank you for your patience and love for the whole time I was juggling family, work and study commitments. Thank you to my best friend, my Mum and to my Dad who never fails to be proud of me (no matter, what I do!). Thanks also to my sister Jo who provided diversion and distraction in times of need. I could not have achieved this without you all tolerating my ups and downs and putting up with me over the past three years.

Chapter 1: Introduction

1.1 BACKGROUND

The nurse practitioner (NP) role was first established in the USA more than 50 years ago, developing and maturing since then (Christian, Dower, & O'Neil, 2007). The NP role was initially developed in response to demands for health care services particularly in rural and underserved areas as a result of physician shortages (Savrin et al., 1991). Over time, the NP role spread to other countries and whilst well-established in the USA, UK and parts of Europe, the NP role in Australia is a relatively recent development. Nurse practitioners are registered nurses who possess expert knowledge, complex decision-making skills and clinical competence (International Council of Nurses (ICN), n.d.) with legislated extensions for expanded practice including diagnosis, prescribing and referral. The NP service model, one of the most important developments in nursing in recent times, provides the opportunity for significant reform in the Australian health care setting (Gardner, 2004). Recent figures show that there are over 1,300 NPs endorsed to practice nationally (Nursing and Midwifery Board of Australia, 2015) working in a variety of specialty areas, with emergency being the single largest subspecialty NP group in Australia (Middleton, Gardner, Gardner, & Della, 2011). In Australia and the UK widespread adoption of the emergency nurse practitioner (ENP) service model was a response to imperatives to improve access and equity for emergency department (ED) patients who were experiencing excessive waiting times for management, diagnosis and discharge (Maurice & Byrnes, 2001). Consequently, the ENP service was primarily focused on management of ED presentations of minor illness and injury, these being the most common ED presentations (Australian Institute of Health and Welfare, 2015).

1.2 RURAL EMERGENCY DEPARTMENTS

Globally, EDs have experienced overcrowding and an increased demand for services, with the greatest increase found in high acuity presentations (Lowthian & Cameron, 2012; Toloo et al., 2011). The causes of this overcrowding are

multifactorial and include not only an overall increase in patient volume but also an increased complexity and acuity of patients making evaluation in the ED more time consuming (Derlet & Richards, 2000). Rural EDs have been particularly impacted by this trend. Whilst major Australian metropolitan EDs experienced a 15% growth in ED presentations, regional areas experienced a 24% increase in presentations for the period 2001-2002 and 2007-2008 (Toloo et al., 2011).

People living in rural areas have shorter life spans, higher rates of disease and poorer health outcomes than those living in major cities (Australian Institute of Health and Welfare, 2014a). Compared to their metropolitan counterparts, the rural population is more likely to have high cholesterol, be overweight and lead sedentary lifestyles and engage in risky behaviours like smoking and drinking alcohol in harmful quantities (Australian Institute of Health and Welfare, 2014a). In country areas there are more physically dangerous occupations and risks associated with driving; for example longer distances, higher speeds and environmental hazards that contribute to higher accident rates, injury and death (Australian Institute of Health and Welfare, 2014a). It is likely that these risk factors in combination with inequality in access to health services are responsible for poorer rural health outcomes (Australian Institute of Health and Welfare, 2014c) for rural populations.

The rural context impacts on the capacity of health services to deliver care. Although there are almost twice as many Australian rural hospital-based emergency facilities as there are metropolitan emergency departments (Baker & Dawson, 2014), there are lower numbers of health care professionals and most rural hospitals do not employ specialist staff within the emergency department. Additionally, health service usage differs between major cities and rural locations which impacts on health services demand for example, there are lower rates of general practitioner consultations and higher rates of hospital admissions for rural areas (Australian Institute of Health and Welfare, 2013).

Traditionally, the provision of health services in rural and remote centres was medically dominated, relying on solo doctors to provide care to patients through long working hours and unsafe on-call arrangements. However more recently, there has been a call for reforms to improve access to care by using new models of care for the delivery of quality care that is effective, appropriate and sustainable (Standing Council on Health of the Australian Health Ministers Conference, 2012).

1.3 NURSE PRACTITIONERS IN THE RURAL EMERGENCY DEPARTMENT

Although there are challenges, there is also abundant opportunities for service innovation in rural health services. A range of innovative service and workforce models have been developed including the NP. This service has been implemented in EDs as a strategy to improve access, efficiency and quality of care for patients (Wilson, Cameron, & Jennings, 2008). Recent evidence has demonstrated that ENP service directly impacts on the quality of health care through improved access to services (Lowe, Plummer, & Boyd, 2013; O'Connell & Gardner, 2012), and that the metropolitan ENP practice scope has been limited to the management of minor injury and illness (Considine, Martin, Smit, Jenkins, & Winter, 2006; Jennings et al., 2008; Lowe, 2010).

The implementation of the ENP service as one step in addressing rural health reform has the potential to directly impact on service outcomes and quality patient care. In rural Australian emergency facilities there is growing use of the service model, with 38% of these departments now staffed by ENPs (Barnason & Morris, 2011). Despite increasing use of the service model, there is a paucity of evidence that is reported in the national and international literature regarding the safety and quality of the service. Robust review of current databases reveal that no experimental or observational studies have been published that specifically focused on evaluation of the effectiveness of the service model in the rural context. Unlike their metropolitan counterparts, in rural EDs the ENP works to their full practice scope across all patient acuity levels.

Clearly then, in acknowledging the paucity of evidence regarding the effectiveness of ENP service in rural EDs, there is a requirement to evaluate the quality of health care for those patients presenting with a complex and significant health care complaint.

1.4 CHEST PAIN IN THE RURAL EMERGENCY DEPARTMENT

Chest pain presentations represent a considerable burden for rural health services. Whilst chest pain is characteristic of acute coronary syndrome (ACS), the majority of patients with chest pain are ultimately found to have non-cardiac diagnoses (Cullen et al., 2012; George, Ashover, & Cullen, 2013; Groarke, O'Brien,

& Go, 2013; Meek, Braitberg, Nicolas, & Kwok, 2012). Not-with-standing the diagnostic outcome, there are considerable costs to health services in evaluating patients who are experiencing chest pain. In Australia, clinicians' practice conforms to the Cardiac Society of Australia and New Zealand and National Heart Foundation of Australia guidelines (CSANZ/NHF guidelines) for the management and treatment of patients with possible or confirmed ACS. These guidelines were most recently updated in August, 2016 (Chew et al., 2016) and whilst published prior to submission of this thesis, the research was conducted prior to their publication and utilised the earlier version of the guidelines (The Cardiac Society of Australia and New Zealand Acute Coronary Syndrome Guidelines Working Group & National Heart Foundation of Australia, 2006)

In the context of increasing health service demand, the challenge for clinicians in caring for this patient cohort is balancing risk and resources to determine an appropriate pathway of care and ED disposition (Parsonage, Cullen, & Younger, 2013). To achieve this, strategies to reduce delays to testing including assessment protocols that expedite early identification of low-risk patients and those that require early specialist review are necessary (Groarke et al., 2013). Invasive diagnostic testing and therapies are only available in metropolitan health services, meaning that rural patients with high acuity diseases must be transferred to larger hospitals for further investigation and management. Unnecessary transfer to tertiary hospitals is disruptive and stressful to patients and their families as well as costly to the health care system (Westfall, Van Vorst, McGloin, & Selker, 2006).

1.5 RURAL HEALTH SERVICES RESEARCH

Rural health services research has largely been shaped by the challenges in the delivery of health care in the context of health reform. The Australian Government Rural Health Workforce Strategy was established under the 1996/1997 Budget (Gausia, Thompson, Lindeman, Brown, & Perkins, 2015) as a response to inequalities in the health outcomes of the rural population caused through limited access to health services and an unequal distribution of health professionals (Humphreys, Wakerman, & Wells, 2006). Through this initiative, funds were invested to establish university departments of rural health with the objective of improving access for rural populations to appropriate services through support,

education and training for rural and remote health professionals (Humphreys et al., 2000).

For this reason, there is a plethora of research that addressed the area of systems for delivering health care (Hollingsworth, 2008; Morley et al., 2007; Mueller, 2002; Runciman et al., 2012; Wakerman et al., 2008). In a recent systematic review of the research output of university departments of rural health, Gausia et al. (2015) identified 182 research articles that had been published since the inception of these departments. Of these, 56% addressed rural health issues with a quarter of these having a focus on Aboriginal health. The remaining research was directed towards study of rural workforce issues and health services policy. Similarly, other research has demonstrated that more than two-thirds of the contemporary rural health research has focused on service needs identification, characterisation of communicable diseases and epidemiological studies (Patterson, 2000).

Whilst this research has been important for beginning evaluation of rural health services, research questions now need to evolve from the processes of care to the outcomes of that care which has now become more accessible through health service reform (Mueller, 2002).

1.6 RESEARCH AIM

Health services are required to deliver safe, high quality care (Lecky, Benger, Mason, Cameron, & Walsh, 2014) and universally, one of the most important indicators is the measurement of the quality and safety of this patient care (Lowthian & Cameron, 2012). This knowledge is essential in motivating changes and improvements for the service (Braspenning et al., 2013). Despite increasing use of ENPs in rural areas, there is a paucity of evidence that is reported in the national and international literature regarding the safety and quality of the service. Robust review of current databases reveal that no experimental or observational studies have been published that specifically focus on evaluation of the effectiveness of the service model in the rural context. There is also a paucity of research that evaluates the model outside of the minor injury and illness context.

The aim of this study was to examine the safety and quality of the ENP service model in provision of care in the rural environment and to evaluate the effectiveness

of the service in the management of patients presenting with undifferentiated chest pain.

To achieve this aim the following null hypotheses were tested:

Hypothesis One – Primary outcome

H_0 For patients presenting to rural emergency departments with suspected or confirmed **acute coronary syndrome** who are managed by the ENP service or standard medical care, there will be no difference in:

(i) Use of evidence based guidelines for management of care as measured by the extent to which this was demonstrated in the clinical record and,

(ii) Diagnostic accuracy as measured by accuracy of electrocardiogram (ECG) interpretation.

Hypothesis Two

H_0 For patients presenting to rural emergency departments with **undifferentiated chest pain** who are managed by the ENP service or standard medical care, there will be no difference in:

(i) Service indicators of

a. Median waiting times

b. Overall length-of-stay in the emergency department for all patients presenting with chest pain

c. Did-not-wait rates

(ii) Diagnostic accuracy as measured by rates of unplanned representation within seven-days

Hypothesis Three

H_0 For patients presenting to rural emergency departments with **undifferentiated chest pain** who are managed by the ENP service or standard medical care, there will be no difference in levels of patient-reported outcomes related to:

i) Satisfaction with care

ii) Quality-of-Life (QoL)

iii) Functional status.

This thesis provides an account of the activities that were undertaken to test these hypotheses and conduct a rigorous and comprehensive study of rural ENP service effectiveness.

1.7 THESIS OUTLINE

The research examined the safety and quality of the ENP service in the management of a patient cohort presenting to rural EDs with complex health needs. By presenting the research processes and outcomes of this scholarly work, the thesis contributes to provide evidence of the effectiveness of ENP service.

At the time that this thesis was commenced the NP service was a relatively novel health reform in Australia and research into this health service model was in the early stages of establishing the services. Concurrently, there were also significant pressures for rural health services to increase access to emergency care by using an appropriately skilled and supported workforce. The remaining sections of this Chapter will illustrate the pressures faced by rural health services in the provision of emergency care and provide an overview of the rural ENP service.

This is a thesis by publication and presents a corpus of original work developed and presented in five manuscripts; two of which have been published, one accepted and currently in press and two manuscripts currently under review. Each of these publications informed the subsequent research processes and has contributed in depth to the knowledge of rural health services, chest pain management and the safety and quality of the ENP service. The thesis represents the methodology and foundation that was used to achieve the research aim which was an evaluation of rural ENP service by means of a well-designed observational study.

Chapter 2 presents a comprehensive and critical review of published research that has evidenced the effectiveness of the ENP service model. This Chapter also includes a review of the evidence associated with risk stratification tools for use in patients who present to EDs with undifferentiated chest pain. The review was conducted to address the applicability and suitability of these tools for use by rural health services. Subsequently, a manuscript entitled: ***"Diagnostic accuracy of risk stratification tools for patients with chest pain in the rural emergency department: a systematic review"*** was reported.

Chapter 3 reports a preliminary audit study also a published manuscript titled "***A retrospective observational study of rural patients with chest pain".*** This study was undertaken to inform data collection and sample selection for the main research. This published article met the following aims: (i) to obtain knowledge about this patient population and the processes of care; and, (ii) to contribute to sample size estimation and anticipated time frame for recruitment for the proposed research.

Chapter 4 describes the research methods for a prospective longitudinal nested cohort study. The Chapter begins with a discussion of the methods and justification for the research approach. Next, the guiding conceptual framework for the research is introduced before presenting the published study protocol. This is reported in the manuscript entitled *"**Effectiveness of an emergency nurse practitioner service for adults presenting to rural hospitals with chest pain: protocol for a multicentre, longitudinal nested cohort study"***. The literature review reported in Chapter 2 evidenced a lack of similar enquiry into ENP service. By publishing the protocol, our study was subjected to external review prior to its commencement. Publication of the protocol also promotes transparency, openness and reproducibility of the study results which strengthened the validity of the study. The Chapter concludes with a discussion on data management and the ethical considerations of the research including potential problems and their management.

Chapter 5 reports the results of the observational study that evaluated multiple outcomes of the rural ENP service in the management of patients presenting with undifferentiated chest pain. Reporting of these results conformed to the data analysis plan that was presented in the previous Chapter and was informed by the conceptual framework that was introduced in Chapter 2. The manuscript that resulted from the study findings is entitled ***"The effectiveness of emergency nurse practitioner service in the management of patients presenting to rural hospitals with chest pain: a multisite prospective longitudinal nested cohort study"***. This manuscript is under peer review.

Chapter 6 presents a critical discussion of the results of this research that is guided by the Donabedian Structure-Process-Outcome theoretical framework. This Chapter draws together the findings of the research and represents the output of this scholarly work which has focused on ENP service research. The final manuscript entitled **"*Perils and pitfalls in conducting rural health services research: a***

***biographical case study*"** reports the critical issues and problems encountered during the conduct of the observational study.

The final Chapter, **Chapter 7** concludes with recommendations made from analysis of the research findings and provides direction for future research in this field.

1.8 CONCLUSION

While the timely delivery of quality patient care in the ED has emerged as one of the most important service indicators to measured in contemporary health care, there are significant gaps in the research that has evaluated ENP service on the outcomes and processes of care for patients. Despite increasing use of the ENP service model in rural health services, there is scant research reported in the national and international literature regarding this service innovation. No experimental or observational studies have been undertaken that have evaluated the effectiveness of the ENP service in the rural context. There is also a scarcity of research that has evaluated the model outside of the minor injury and illness context. The management of patients presenting to rural EDs with chest pain is under researched and poorly reported in the literature. This research will provide new information specific to this service and will assist in providing an evidence base for this innovation at a level that has not been studied before.

This research provides a multi-layered study examining a new service provider in the management of a complex health condition that is patient presentations to ED with chest pain.

Chapter 2: Literature Review

2.1 INTRODUCTION

As demonstrated in the previous chapter ENP service is a relatively novel health reform model in Australia which, in the context of increased demand for services, requires robust study of the impact of this service on patient care and health. This Chapter reports on a comprehensive and critical review of the literature that has evidenced the effectiveness of ENP service. The Chapter also includes a review of the evidence associated with risk stratification tools for use in patients with suspected acute coronary syndrome. A manuscript reporting a systematic review of the diagnostic accuracy of these tools that has been accepted for publication in *Emergency Medicine Australasia* is presented. This review was conducted to address the applicability and suitability of these tools for rural health services.

2.2 EMERGENCY NURSE PRACTITIONER EFFECTIVENESS

Whilst there is an abundance of literature reporting the evidence of success of ENP service in the international and national literature (Blunt, 1998; Byrne, Richardson, Brunsdon, & Patel, 2000; Chang et al., 1999; Sakr et al., 1999), the aim for this literature review was to identify contemporary robust research evidence of the quality and safety of the ENP service model.

2.2.1 Literature search strategy

The aim of this literature review was to establish the national and international evidence relating to the effectiveness of the emergency nurse practitioner service. To achieve this, a systematic and comprehensive search of health related databases was conducted in July 2013 and again in April 2016. The following databases were searched (in alphabetic order): Academic Search Elite; Cumulative Index to Nursing and Allied Health Literature; Cochrane Library; Current Contents Connect; EBSCO host; E-Journals; Google Scholar; Health Reference Centre; Medline; ProQuest; ProQuest Dissertations and Theses; PubMed; ScienceDirect; Web of Science.

Key search themes and keywords for each strategy were developed and each term, using Boolean phrase searching where appropriate, was searched within the

fields of title, abstract, keywords and references. Search terms were used singularly and were combined to yield results. Searches were expanded and refined by using the Boolean operators AND and OR. Truncation was used where appropriate to find terms that may have various forms, for example, nurs*e*, nurs*ing* and nurs*es*. Proximity searching, using the "near" and "within" operators, was also utilised.

The initial results from the database searches were screened using the title and abstract by the author for relevance to the study aims. Full text articles were then obtained and reviewed. The reference lists for these articles were hand searched for additional articles not already found.

Search terms and keywords

Search terms used were (in alphabetical order): accident and emergency; advanced practice nurse; advanced practice nurses; advanced practice nursing; benefit; benefits; capability; casualty; effectiveness; efficiency; emergency; emergency care; emergency nurse practitioner; emergency nurse practitioners; emergency room; emergency rooms; evaluation; impact; patient satisfaction; performance; quality of health care; minor injury clinic; minor injury clinics; nurse practitioner; nurse practitioners; results.

Inclusion criteria

All individual research based peer-reviewed journal articles published in English on or after 1 November, 2006 were included in the search. The review was limited to this time frame for two reasons. Firstly, by limiting articles to the proceeding ten years, the time frame is in alignment with recommended maximum time frame for the age of works to be included for quality literature reviews (Cronin, Ryan, & Coughlan, 2008). Finally and most importantly, the current review builds upon the first published systematic review that included studies published prior to November 2006 that evaluated emergency nurse practitioner effectiveness (Carter & Chochinov, 2007). This literature review includes new studies which were not included in Carter and Chochinov's seminal research.

Primary research studies that evaluated nurse practitioner effectiveness in the emergency setting were selected to allow for a homogenous population for comparison of studies.

Search outcomes

A search of the databases retrieved 1079 articles for potential inclusion in the literature review. Of these, 567 articles were duplicated within databases, leaving 512 articles for further inspection. After review of the abstracts, 37 articles were left that met inclusion criteria. A hand search of the references of these full-text articles yielded a further two articles that were included in this review. The final outcome was 39 articles that were fully appraised and a narrative analysis of these studies will be included in this review. See Figure 1 for flowchart relating to search outcomes.

In order to achieve the aim of this literature review in establishing the national and international evidence relating to the effectiveness of the ENP service, this section commences with a critique of the three systematic reviews and follows with a themed narrative analysis of the remaining studies. In that analysis three key themes were identified and will framework the report: organisational effectiveness, patient satisfaction and clinical effectiveness.

2.2.2 Systematic reviews of emergency nurse practitioner effectiveness

The systematic reviews that have synthesised the evidence regarding the clinical effectiveness of the ENP service incorporated all relevant studies from the period 1979 to 2013 (Carter & Chochinov, 2007; Jennings, Clifford, Fox, O'Connell, & Gardner, 2015; Wilson, Zwart, Everett, & Kernick, 2009).

The most frequently cited review (135 times according to Google Scholar), by Carter and Chochinov (2007) aimed to evaluate the impact of NPs in the emergency department. To achieve this aim, researchers provided a narrative synthesis of 36 studies that examined NPs (either qualified or in training) and the effect on four key outcome measures: cost, quality of care, satisfaction and wait times. The overall cost was demonstrated to be higher for NP care, which Carter and Chochinov attributed partially to a lack of volume of patients seen by NPs because of restrictive protocols. Nurse practitioners were found to perform equally well in x-ray interpretation and better at documentation, appropriateness of referrals and following protocols when compared to medical residents. These researchers also asserted greater patient

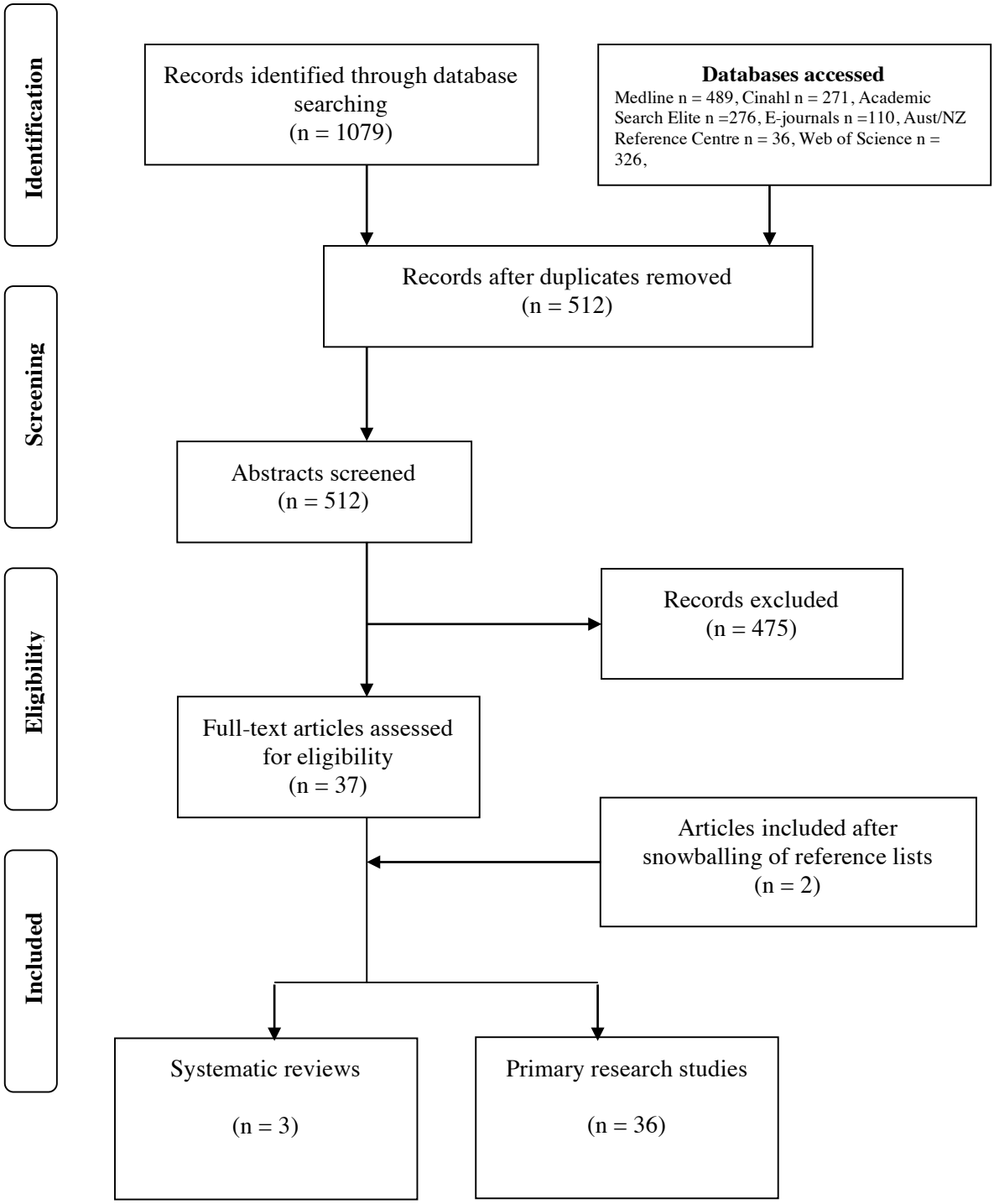

Figure 1 Search flowchart

satisfaction for patients managed by NPs that was derived from additional patient contact time, improved communication and shorter length of stay. Most of the included studies focused on NPs in a minor injury or fast track setting. The results of this review suggest that the use of NPs in this context improve waiting times and patient satisfaction, with little or no impact on quality of care. Several weaknesses of the Carter and Chochinov review are identified including heterogeneity of study designs and outcome measures. Yet, the major limitation of this review was that there was no attempt to compare the roles of the ENPs being studied to ensure that they were equivalent. The studies included in the review did not evaluate ENP's exclusively but included nurses in training. Even though there are noticeable differences in the level of practice and legislated extensions to practice between qualified and non-qualified ENPs the data were analysed as though they were equivalent.

The second systematic review was also conducted in the context of minor injury and illness in adult EDs (Wilson et al., 2009). By performing meta-analysis of pooled data from nine studies including two RCTs, Wilson et al. (2009) demonstrated no significant differences in the clinical effectiveness of ENP service compared to the standard care model. For the standard care model, management of ED patients was lead by a medical officer. Primary outcomes studied included waiting time, referral to other practitioners, unplanned representation, cost effectiveness and patient satisfaction. Using a strong methodology with transparent research processes, Wilson et al. (2009) concluded that there was no significant difference between the effectiveness of ENP and junior doctors. The researchers asserted that this finding needs to be interpreted with caution because of the poor to fair methodological quality of the studies included and the lack of homogeneity of outcome measures. The need for more high-quality research that evaluates suitable outcome measures to fully evaluate ENP service was highlighted by the results of this review. In the same way as the previous review, this research is limited by the use of "nurse practitioner like" services and additionally, the ambiguity in the role and qualifications required between countries.

The most recent systematic review (Jennings et al., 2015) aimed to build upon the two previous reviews by including research that had been undertaken since the original two reviews (Carter & Chochinov, 2007; Wilson et al., 2009). Jennings et

al. (2015) replicated Carter and Chochinov's 2007 search strategy to identify relevant studies. Fourteen studies, consisting of two systematic reviews, two RCTs and 10 observational studies, were included in the narrative synthesis using the same four key outcome areas of cost, quality of care, satisfaction and wait times. Jennings et al. (2015) cautioned that their review was impeded by the paucity of high quality research; however, they found a positive impact on quality of care, patient satisfaction and waiting times with the use of ENP service but were unable to determine the impact of the service on cost. Similar to the previous systematic reviews (Carter & Chochinov, 2007; Wilson et al., 2009), Jennings et al. (2015) also included studies that evaluated nurses with varying practice scopes and qualifications.

Clearly, the validity of the findings of each systematic review are open to a considerable degree of criticism. The comparator against which ENPs were evaluated was invariably a medical practitioner. Marked heterogeneity between the qualifications of the medical practitioners studied, with a reliance on comparisons with junior doctors who do not share the advanced skills or practice privileges afforded to ENPs was noted. This assumes that medical practitioners are the "gold standard" in the delivery of emergency care, which is open to debate. Continuing this idea, outcome measures used to evaluate the effectiveness of ENP are generic and may not identify the unique contribution that ENPs provide. The other major limitation of these studies was a lack of consistency in the clinical skills and level of interventions of the ENP services studied because of the considerable variance in the definitions and scope of practice internationally. Much of the research (Carter & Chochinov, 2007; Jennings et al., 2015; Wilson et al., 2009) has used nurses who were not practicing to the full scope of the role, for example training ENPs or nurse practitioner candidates. Although these nurses were using advanced practice skills the majority worked within the boundaries of a registered nurse.

2.2.3 Themed analysis

Organisational effectiveness

The beneficial effect of an ENP service in meeting organisational goals or key performance indicators has been advocated in both the Australian and international literature. Waiting time, the time from triage to treatment by the assigned clinician, and the time from triage to discharge of the patient (LOS), are recognised indicators

of the efficiency of an emergency service (Bernstein et al., 2009). The influence of ENPs on organisations reaching performance targets using the outcomes of reduced waiting times for assessment and treatment (Considine, Martin, Smit, Winter, & Jenkins, 2006; Ducharme, Alder, Pelletier, Murray, & Tepper, 2009; Fry, Fong, Asha, & Arendts, 2011; Jennings et al., 2008; Lutze, Ratchford, & Fry, 2011; Steiner et al., 2009), overall length of stay (LOS) (Considine, Kropman, & Stergiou, 2010; Ducharme et al., 2009; Jennings, Mckeown, O'Reilly, & Gardner, 2013; Steiner et al., 2009; Thompson & Meskell, 2012; van der Linden, Reijnen, & de Vos, 2010) and proportion of patients who left without being seen (LWBS) (Colligan et al., 2011; Ducharme et al., 2009; Nash, Zachariah, Nitschmann, & Psencik, 2007)is consistently reported.

Research on the impact of the ENP service on organisational effectiveness is diverse and covers studies from Ireland, the Netherlands, Canada and Australia. In a study of 964 patients with minor injuries and illness, Thompson and Meskell (2012) noted shorter LOS (mean 51minutes compared to 83 minutes for whole ED), which was equal to the times recorded for emergency consultants. Correspondingly, van der Linden et al. (2010) also found that the mean LOS was significantly longer for doctors than ENPs (85 minutes for doctors and 65 minutes for ENPs; $p<0.001$). Two large Canadian observational studies (Ducharme et al., 2009; Steiner et al., 2009) noted a reduction in waiting times by using ENP service. Ducharme et al. (2009) undertook retrospective case audit to assess the impact on patient flow within six Canadian EDs after the introduction of ENPs and physician assistants (PAs). Specifically, patients who were cared for by ENPs were found to be 2.1 (95% CI 1.6-2.8, $p< 0.05$) times more like to be seen within wait-time benchmarks. Length-of-stay was reduced by 48.8% (95% CI 35.0%-62.7%, $p<0.01$). This service initiative was found to both directly (through direct patient care) and indirectly (by being on duty) reduce overall waiting times and LOS for all patients presenting to the ED.

Similarly, Steiner et al (2009) found an increase in the volume of patients seen per shift (12%, $p<0.001$). The prospective observational study, compared differences during intervention shifts (when the ENP was working alongside an emergency physician) and control shifts (care managed by an emergency physician alone). Shortest wait times and LOS was recorded in the group of patients who were managed by the ENP, particularly for those patients who could be managed

autonomously, then for any other cohort. The results of this study, though, have serious issues relating the generalisability and external validity of these results. Within this department, the emergency physician retained the ultimate decision-making authority and the ENP scope of practice limited autonomous practice to a very specific cohort of patients. The majority of the patients who were included in the autonomous management group (80%) were planned return visits for intravenous antibiotic administration, a simple task-orientated occasion-of-service and as such could be expected to have short LOS.

Although the Ducharme et al. (2009) and Steiner et al. (2009) studies found organisational gains through the introduction of the ENP service, these results do not necessarily support the effectiveness of the service. Whilst shorter waiting times and LOS for patients managed in the ENP service model were demonstrated, these advancements may be explained by the ENP service being additional to the existing health care team. By introducing the ENP service, the number of providers able to assess and treat patients increased.

Nurse practitioner practice is a recent health service innovation in Australia and New Zealand. Accordingly, several studies (Considine, Martin, Smit, Winter, et al., 2006; Fry et al., 2011; Jennings et al., 2008; Lutze et al., 2011) were undertaken to establish the safety and efficiency of the emerging service by evaluating the care provided by ENPs in training to patients with minor injury and illnesses. Considine et al. (2006) found no significant differences in median waiting times, treatment times or ED LOS between patients managed by the ENP student and those managed in a traditional medical model of care; however, subsequent studies demonstrated statistically significant improvements in waiting times and LOS with the introduction of training ENPs to a service (Fry et al., 2011; Jennings et al., 2008). Through introduction of a training ENP service, Fry et al. (2011) found significant differences in waiting time (median 38 minutes versus 59.7 minutes, $p<0.01$) and length-of-stay (median 207 minutes versus 213 minutes, $p<0.01$) compared to the previous year. Jennings et al. (2008) also found improvements in waiting time (median 12 minutes versus 31 minutes, $p<0.001$) and length-of-stay (94 minutes versus 170 minutes, $p<0.001$) for patients cared for by training ENPs when compared to those managed by the standard model of care (that care which was lead by a medical officer). These findings provide evidence of organisational effectiveness of a nascent service for the

management of minor injuries and illnesses in Australia. Of note, now that the model is established in the Australian context, the findings of these studies are not applicable in evaluation of the model.

The more established, evolved ENP role in Australia and New Zealand has continued to meet organisational goals for in patients with minor injury and illness who are seen by ENPs (Colligan et al., 2011; Considine et al., 2010; Jennings et al., 2013). Jennings et al. (2013) demonstrated short waiting times (median 14 minutes, IQR 7-33) for patients managed by a well-established ENP service. Median LOS for patients discharged home with treatment by this ENP service was 131 minutes (IQR 82-200) with 95.1% of patients complying with the national 4-hour non-admitted patient targets (Baggoley et al., 2011). These findings were subsequently corroborated in a recent RCT that evaluated the quality of care for patients presenting to a metropolitan fast track unit with pain (Jennings, Gardner, O'Reilly, & Mitra, 2015a). Jennings et al. (2015a) found no statistically significant difference in the waiting times (mean 41.5 minutes versus 39.4 minutes, p=0.55) or LOS (mean 143.5 minutes versus 146.7 minutes, p=0.71) for patients managed by either ENP service when compared with the standard care model. Colligan et al. (2011) and Considine et al. (2010) found comparable results for the organisational effectiveness of an ENP service. Colligan et al. (2011) found significantly shorter LOS (median LOS shorter by 40 minutes) was demonstrated for the group of patients seen by ENPs compared to those who were seen by emergency registrars. Considine et al. (2010) also found that patients managed by emergency physicians and ENPs had the shortest LOS, whereas patients managed by junior doctors and interns had significantly longer LOS ($p<0.001$). The main limitations of these studies are that there is no consideration of the variability in the skills, knowledge and decision-making abilities of the clinician groups studied. Doctors with lower levels of experience require "sign-off" by a senior colleague for patients prior to discharge that may account for the increased LOS. Additionally, there is marked difference in the responsibilities of these clinicians; medical staff are often diverted to other clinical areas for higher acuity patients, whilst these ENPs have lower levels of interruptions with a clear focus on the management of minor injury and illness.

In addition to improvements in waiting times and LOS, a reduction in the proportion of patients who leave without being seen can also be used as a measure of

the impact of a service initiative. The implementation of an ENP service in the minor injury or Fast Track area of metropolitan EDs has been demonstrated to result in a decrease in the proportion of patients who LWBS (Colligan et al., 2011; Ducharme et al., 2009; Fry et al., 2011; Nash et al., 2007). Nash et al. (2007) found a statistically significant difference in the proportion of patients who LWBS (3.9%, 95% CI 3.70-4.10) in the ENP-led Fast Track area when compared to the main ED (6.7%, 95% CI 6.45-6.97) ($p<0.001$). Colligan et al (2011) and Ducharme et al. (2009) also reported similar rates after the introduction of an ENP service in the management of minor illness and injuries. Although these studies demonstrated a service improvement, it is important to note that for all departments included in these studies, staffing levels were generally higher when ENPs were working, with the ENP service being additional to normal staffing, which may account for these improvements.

Although the difference in responsibilities between ENP and medical staff may account for some of the improvements in organisational outcomes, ENPs may utilise strategies that lead to statistically significant time-related advantages in the management of patients with minor injuries. Wood et al. (2007) found shorter LOS (30 minutes, $p< 0.01$) and time to sedation (13 minutes, $p< 0.05$) for paediatric patients undergoing procedural sedation and analgesia (PSA) when compared to senior medical colleagues (attending physicians and emergency fellows). These improvements may have occurred simply because ENPs, being experienced nurses, are familiar with the role and demands on other emergency nurses and as such are more likely to facilitate a timely, cooperative approach by assisting to prepare for PSA by establishing intravenous access, drawing up medications and attaching monitoring. However, Wood et al. (2007) found that ENPs in their study had embraced contemporary evidenced-based practice in the use of pharmacological agents that provided deeper anaesthesia with shorter recovery times and adjuncts to anaesthesia (local anaesthetic and blocks) in preference to the superseded strategies preferred by the medical officers studied. For example, medical officers were more likely to use more traditional medications like morphine and fentanyl for sedation, whereas these ENPs were more likely to use the more contemporary drug, ketamine, resulting in shorter length of sedation and recovery time.

The literature evaluated for this review provides evidence of the effectiveness of the ENP service model in meeting service outcomes such as reduced waiting

times, LOS and proportions of patients who LWBS. Whilst these findings have mostly arisen from study of the service in the minor injury and illness context, the evidence demonstrating shorter waiting times for ENP service may confer support for the utilisation of the service in the management of higher acuity, time sensitive presentations like chest pain.

Patient satisfaction

The acceptability of the ENP service has been clearly established with consistently high levels of patient satisfaction reported in the literature (Dinh, Walker, Parameswaran, & Enright, 2012; Hart & Mirabella, 2009; Jarvis, 2007; Jeanmonod, Delcollo, Jeanmonod, Dombchewsky, & Reiter, 2013; Jennings, Lee, Chao, & Keating, 2009; Lutze, Ross, Chu, Green, & Dinh, 2013; McDevitt & Melby, 2015; Sandhu, Dale, Stallard, Crouch, & Glucksman, 2009; Thrasher & Purc-Stephenson, 2008; Wilson et al., 2008). The majority of patients are willing to be treated by an ENP (Hart & Mirabella, 2009; Jarvis, 2007) and patients who have experienced a previous exposure to care from an ENP service are willing to be treated again by an ENP (Hart & Mirabella, 2009; McDevitt & Melby, 2015). Whilst the findings of these studies support the acceptance of the service, both the Hart and Mirabella and Jarvis studies used a data collection tool that was yet to be validated and which may affect the reliability of these results.

Other researchers have demonstrated that patients find ENPs competent in providing care (93%) and are satisfied with their overall care (91.3%) (Wilson et al., 2008). Consistently higher levels of patient satisfaction with ENP service, when compared to doctors working in this area have been demonstrated (Dinh, Enright, Walker, Parameswaran, & Chu, 2013; Dinh et al., 2012; Jennings et al., 2009). Jennings et al. (2009) reported significant differences in 12 out of 16 survey questions ($p<0.05$) and concluded that ENPs were found to be thorough and reassuring, with patients reporting having enough time to discuss their concerns. The 12 questions that favoured ENP service related to the clinician being interested in the person, thoroughness, being less worried after seeing the clinician and having enough time to discuss concerns in detail.

Similarly, other studies provide evidence that patients managed by ENP service rate their care as “very good” or “excellent”. Studies of convenience samples of patients have used a Likert scale in determining patient satisfaction with ENP service

(Dinh et al., 2012; Lutze et al., 2013; McDevitt & Melby, 2015). McDevitt and Melby (2015) used a validated patient questionnaire to survey patients (n=111) who attended a nurse-led rural minor injuries unit in the UK and reported that most patients (81.3%) found the overall quality of the ENP service to be "excellent". Lutze et al. (2013) surveyed 353 patients and compared between two different models of care for fast track patients. Patients were recruited after attendance at a tertiary hospital ED staffed by doctors (senior resident medical officers or registrars) or a smaller urban ED staffed by ENPs. Overall, 86% (95%CI 82-89%) of fast track patients rated their care as "very good" or "excellent". Patients managed by the ENP service were found to be 2.5 times more likely to have higher satisfaction scores compared to those in the doctor group. Selection bias needs to be considered for both studies as only around a third of eligible patients completed the survey. Furthermore, a major limitation of the Lutze et al. (2013) study was the failure to account for the major differences in the study settings which could also have led to significant bias.

In the same way, although Dinh et al. (2012) also established that a higher proportion of patients managed by the ENP service rated their care as 'excellent' there were several important limitations that may affect both the internal and external validity of this finding. This study used a convenience sample of 236 patients presenting to an Australian metropolitan fast track unit who were managed either by ENP service or the standard care model. The unit only employed one ENP and as such it evaluated satisfaction with the individual clinician rather than an ENP service. Additionally, although this study found high levels of satisfaction for both groups of patients, the effect of excluding patients who had waited longer than two hours prior to treatment may have introduced bias. Dinh et al (2013) performed secondary analysis of this data set and found that patients waiting one hour or less had higher satisfaction scores compared to those who waited longer. Correspondingly, other evidence supports that reduced waiting times are associated with increased levels of patient satisfaction (Ducharme et al., 2009; Thrasher & Purc-Stephenson, 2008). Jarvis (2007) also studied the effect of waiting time as a confounding variable and asserted that whilst high levels of patient satisfaction were maintained, although as times increased patients were more likely to rate the service as 'very good' rather than 'excellent'.

Other researchers have demonstrated high levels of satisfaction for ED patients managed by standard care or ENP service (Jeanmonod et al., 2013; Nash et al., 2007; Sandhu et al., 2009; Thrasher & Purc-Stephenson, 2008). Jeanmonod et al. (2013) found that the majority of patients were highly satisfied, felt cared about, were kept aware of tests and had their problems and follow-up explained. No significant difference between health care professionals was shown when comparison was made between doctors and 'mid-level' providers (a group that included five physician assistants and a single ENP). However, the validity of this study is compromised by the lack of a consistent intervention with differences in the roles of health care providers unrecognised in this study design.

Problems with the validity of the findings of a study of patient satisfaction by Nash et al. (2007) is also evident. Nash reported that, of those who participated in their study, 100% of patients who were managed in an ENP-led fast track reported the quality of care as either "good" or "excellent". However, the study was compromised by participant bias, which was introduced by a low response rate in self-selected patients.

In contrast, Thrasher and Purc-Stephenson (2008) conducted a well-designed study that aimed to evaluate the full dimensions of the NP role, including the substance of nursing care and its influence on patient outcomes. This cross-sectional study was undertaken over a one-week period in Canada using a diverse and representative cohort of patients from six different EDs with differing geographical and contextual characteristics. Selection and social desirability bias was controlled for by using a research assistant to invite patients to participate in the study after care had been completed by the ENP rather than having the NP ask patients to complete the survey. Although a small study (n=142) there were high numbers of patients who agreed to participate in the study (91.6%) and a high response rate (80.3% returned questionnaires) was achieved.

This survey identified three components of ENP care that the researchers labelled "Attentiveness" (satisfaction with the personal attention received from the NP), "Comprehensive care" (satisfaction with the care or treatment received) and "Role clarity" (understanding of the NP role). Thrasher and Purc-Stephenson (2008) identified that the majority of patients would prefer to see the ENP and that the ENP

was attentive and provided comprehensive care. Patients who were treated by the ENP demonstrated a good understanding of the role.

Sandhu et al. (2009) also studied these nuances of ENP care, by using a novel approach to comparing the communication skills and levels of patient satisfaction between ENPs and doctors managing minor injury and illness at an inner city ED in the UK. In conjunction with the use of a validated patient satisfaction questionnaire, patient consultations were videotaped and subsequently coded using a formal analysis system that had previously been validated for nurse-patient interactions. From this, researchers contended that ENPs were found to focus on patient education and counselling that led to higher levels of patient satisfaction when compared to ED doctors.

To summarise the findings of the literature that have evaluated patient satisfaction as an outcome of care, high levels of patient satisfaction with ENP service are reported. Patients find the service acceptable, understand the role and demonstrate confidence in the ability of nurse practitioners in the emergency context. However, there are problems drawing conclusions from the international studies (Hart & Mirabella, 2009; Jarvis, 2007; Jeanmonod et al., 2013; McDevitt & Melby, 2015; Sandhu et al., 2009; Thrasher & Purc-Stephenson, 2008) as there is no standard definition of nurse practitioners and specifically in the UK the NP title is not protected by legislation.

Clinical effectiveness

The studies identified in this literature review were found to have examined the clinical effectiveness of ENP service though evaluation of the areas of achieving timely analgesia, the application of clinical tools, diagnostic reasoning in complex case presentations, adherence to evidence-based guidelines and the level of diagnostic accuracy in terms of missed injuries and unplanned representations.

Timely analgesia is one of the key clinical quality indicators of an emergency service. A recent retrospective study (Jennings, Kansal, O'Reilly, Mitra, & Gardner, 2015) found for patients managed by an ENP service the median time to analgesia was 25 minutes (IQR 12-50), with 61.3% (95%CI 51.4-70.6) of patients receiving analgesia within 30 minutes (the national clinical target). These findings were subsequently strengthened by the findings of a RCT (Jennings, Gardner, O'Reilly, &

Mitra, 2015b) that evaluated the effect of ENP service on time to analgesia for 206 patients with any triage complaint of pain who were allocated to the fast track of a tertiary ED. Emergency nurse practitioner service was compared to standard care which was led by emergency registrars allocated to work exclusively in fast track. Jennings et al. (2015b) found a greater proportion of patients with pain received analgesia within 30 minutes when managed by the ENP group (49.2%) versus the standard care group (29.7%). The mean (±SD) time from being seen to analgesia was 25.4 minutes (±39.2) for the ENP group and 43.0 minutes (±35.5) for the standard care, a difference of 17.6 minutes (95% CI = 6.1 to 29.1 minutes; p=0.003).

Clinical tools are often used to support the rational and cost-effective utilisation of diagnostic investigations. Several studies have evaluated the effectiveness of ENPs in the application of clinical tools and/or guidelines (Dewar & Corretge, 2008; Hopkins, 2010; Lau, Kerr, Law, & Ritchie, 2013; Tsai, Sullivan, Ginde, & Camargo, 2010). Dewar and Corretge (2008) demonstrated the clinical ability of ENP service in the application of an evidence-based protocol incorporating the Wells score, a validated tool to predict the likelihood of deep vein thrombosis (DVT). By following the protocol, ENPs were correctly able to exclude the diagnosis of DVT; there was a low incidence (1.04%, 95% CI 0.41-2.65%) of confirmed DVT in patients with negative testing. Whilst these findings may provide support for the clinical effectiveness of ENP service, it could be expected that all clinicians should achieve the same results with application of the evidence-based protocol.

Refuting this assumption, Hopkins (2010) found that the adherence to clinical guidelines by both ENPs and doctors was lacking and contended that patients may not have received appropriate care following a study that evaluated the application of the Ottawa Ankle Rule (OAR) in a minor injuries unit. The OAR has been developed to assist clinicians to determine the need for X-ray in patients who present with an acute ankle or mid-foot injury. Although Hopkins' findings are disconcerting they must be reviewed in the context of a compromised study design that failed to include data on x-ray utilisation. Whilst Hopkins claimed the rules were not applied, because of a lack of documentation of their application, the research objectives were not met. To achieve this, it was necessary to study the proportion of patients with a positive OAR feature (which indicates the need for an x-ray) and those without a positive

feature who had an x-ray performed. A more recent prospective observational study (Lau et al., 2013) of 227 patients presenting with a suspected ankle and/or foot injury found that the majority of patients (85.6%) had an x-ray performed, whilst only 78.7% of the sample had a positive OAR feature.. Lau et al.'s (2013) study compared the application of the OAR by ENPs and emergency doctors consisting of physicians, registrars, hospital medical officers and interns. Lau et al. (2013) found that although not statistically significant, patients assessed by that ENPs were less likely to have a positive OAR feature (70.6% versus 82.1%). Despite this, they found that ENPs requested x-rays at a similar rate to emergency doctors.

Adherence to evidence-based guidelines by ENPs has been reviewed in a large (n = 4029) retrospective multicentre study involving 63 urban EDs in the USA (Tsai et al., 2010). Researchers aimed to evaluate the quality of care provided by "mid-level providers" (MLPs), a group that included both physician assistants (PAs) and ENPs, in the management of adult patients presenting with asthma. Researchers concluded that patients managed by autonomous MLPs were less likely to receive guideline-concordant care and identified opportunities for improvement. Specifically, autonomous MLPs were found to be less likely to administer inhaled β-agonists within 15 minutes of arrival (OR 0.2; 95% CI 0.1-0.7), less likely to prescribe systemic corticosteroids at discharge (OR 0.4; 95% CI 0.2-0.9) and more likely to prescribe inappropriate antibiotics at discharge (OR 2.1; 95% CI 1.1-4.1) when compared to physicians. A major limitation of this study was that researchers combined patients seen by PAs and ENPs into one group, mid-level providers (8%, n=319) group prior to data analysis. Whilst a lack of adherence to guidelines by MLPs was demonstrated, only 27 (0.66% of the total sample) of these patients were managed by ENPs that leads to uncertainty about the findings in terms of the actual adherence to guidelines by these ENPs. Furthermore, this was not a homogenous group and PAs and ENPs have different legislative and practice frameworks.

In a first of its kind study, the diagnostic reasoning abilities of NPs and medical registrars when managing a complex case were compared using a complex case scenario (Pirret, Neville, & La Grow, 2015). The study recruited NPs (n=30) and doctors (n=16) working in multiple clinical specialties in New Zealand. The case scenario presented a real case that was identified as being a complex case with diagnostic uncertainty. Clinicians were compared for the number of correct

diagnoses, problems and actions identified to those determined by an expert panel. Although the NPs studied were relatively inexperienced (mean years of NP experience 2.2 years; 95%CI 1.60–2.80), diagnostic reasoning abilities did not differ between NPs and doctors in determining the correct diagnosis (54.7% versus 61.9%), problems (53.3% versus 56.3%) and actions (35.8% versus 34.4%) as determined by the expert panel. Analysis revealed no difference between these groups (diagnoses 95%CI: 1.76-0.32; p=0.17; problem $\chi^2 = 0.00$, p=1.0; or actions 95%CI: 1.23-1.58, p=0.80).

Continuing the evaluation of the clinical effectiveness of ENP service, there is an abundance of evidence in the literature that focuses on diagnostic accuracy primarily through research that measures unplanned representations and missed fractures for patients presenting with minor injury and illness. Accurate diagnosis is essential to ensure high quality care that is efficient with clinical resources. Using the findings of a retrospective review of 1150 presentations to a paediatric ED, researchers found that compared to ENPs, the odds of representation were higher if seen by a junior (OR 2.26) or senior (OR 2.74) medical trainee (Feetham et al., 2015). Although this finding supports the quality of ENP service, the patient cohorts were demonstrated to be significantly different in complexity with the ENPs managing higher rates of older children with less urgent presentations.

Similarly, clinical effectiveness of ENPs can also be evaluated by observing the rates of unplanned representation rates to an emergency service. Although there are inconsistency of time measures between the studies that have examined unplanned representations to the ED when patients are cared for by ENPs, rather than in the traditional medical model, there is no difference in the likelihood (Colligan et al., 2011; Dinh et al., 2012) or it is less likely (Nash et al., 2007) that they will represent to the ED. Nash et al. (2007) and Colligan et al. (2011) reported rates specifically for patients managed by the ENP service at approximately 2%.

A recent observational study (Lee et al., 2014) of 200 adults with isolated limb injuries presenting to a large metropolitan hospital in Australia compared the diagnostic accuracy of x-ray interpretation of six ENPs and 10 consultant emergency physicians against the findings of a consultant radiologist (the gold standard). Lee et al. (2014) found a very high level of agreement (weighted Kappa of 0.83) on the presence of a fracture between ENP and emergency physicians. Thompson and

Meskell (2012) suggested that ENPs had an equal if not better diagnostic accuracy rate compared to medical colleagues by finding that NPs had the lowest rate of missed fractures (ENP 0.2%, senior house officer (SHO) 1.5%, registrar 1.8%) and false positives (ENP 2.4%, SHO 3.9%, registrar 4.4%) for health professionals working in the ED.

Other studies have also supported the assertion that ENPs achieve high diagnostic accuracy. Lau et al. (2013) reported an overall missed fracture rate of 1.1% and concluded that NPs were less likely to miss a fracture during initial ED assessment compared with ED-based registrars (0.0% versus 28.6%; p=0.013). Colligan et al (2011) found a missed injury rate of 1% (95% CI 0-3%) for both ENPs and doctors. Similarly, van der Linden et al. (2010) conducted a large (n= 1,482) retrospective cohort study of patients with minor injury and illness and found no statistically significant difference for health professionals, with a missed injury rate of 2.7% for ENPs and 1.2% for doctors (RR 0.4; 95% CI 0.031-1.591). The severity of these misdiagnoses was calculated by using a validated scoring system that quantifies errors on a scale of one (a minor problem) to seven (an error requiring immediate intervention). The majority of the missed injuries in this study were of low clinical significance (median score 2) with no diagnostic error scoring five or greater. Although these results demonstrate a high level of diagnostic accuracy, it is worth noting that confounding these findings is that the authors reported that the ENPs studied had low levels of experience that may limit the generalisability of these results to other services.

The diagnostic accuracy of ENPs in the performance of ED ultrasound investigations has been studied. In a unique study undertaken in an American trauma centre ED (Henderson, Ahern, Williams, Mailhot, & Mandavia, 2010) ENPs demonstrated a high degree of adequacy and accuracy in performing focussed bedside ED ultrasound examination. These investigations included examination of the renal tract, gallbladder, aortic, echocardiogram, obstetric and focused assessments with sonography for trauma. Researchers performed an audit of 229 bedside ultrasounds performed by five ENPs and concluded that these ENPs achieved a sensitivity level of 93% and a specificity level of 98%. Another recent study (Atkinson, Madan, Kendall, Fraser, & Lewis, 2014) evaluated the accuracy of 10 ENPs who had completed a two-hour training session in the ultrasound detection

of soft tissue foreign bodies. ENPs were able to detect soft tissue foreign bodies with a sensitivity, specificity, positive predictive value and negative predictive value of 78.3%, 50%, 82% and 43% respectively. Even though the findings of both studies highlight the ability of ENPs in learning procedural skills, these findings do not provide evidence to support the effectiveness of ENP clinical decision making.

The impact of ENP service on referrals of patients to a tertiary hand trauma service in Ireland had been studied (McGoldrick, Damkat-Thomas, & Lewis, 2011). Researchers developed a scoring system that objectively evaluated the quality of the referral using standardised criteria and found no significant differences in the quality of referrals from either ENPs or doctors. Subsequently, the outcome of the patient episode and appropriateness of the referral was judged by the receiving surgeon. A statistically significant (70% of all inappropriate referrals, p=0.042) proportion of referrals deemed inappropriate by the surgeon were generated by ENPs. However, performance bias may have been introduced into this finding, as there was no attempt to blind the surgeon as to the referring clinician.

The literature that has evaluated the clinical effectiveness of ENP service provides further support for the service. The service performs well in meeting the clinical quality indicator of timely analgesia for ED patients and uses clinical tools efficiently in the utilisation of diagnostic investigations. Although ENP use of evidence-based guidelines has not been proven, there were major limitations in the study methodology because of the combination of a small group of ENPs with a group of physician assistants to create a "mid-level provider" cohort of patients. The diagnostic reasoning abilities and diagnostic accuracy of NP service compares well with that of their medical colleagues.

2.2.4 Summary of the literature evaluating ENP service effectiveness

The literature has evaluated the effectiveness of the ENP service in the areas of organisational effectiveness, patient satisfaction and clinical effectiveness (see Table 1). The findings support a service that is timely with a beneficial effect on organisational outcomes that include decreased waiting times, length of stay and the proportion of patients who left without being seen. Evidenced in the evaluation of ENP practice is an acceptance of the service with high levels of patient satisfaction. The processes of care employed by ENPs indicate clinical effectiveness in the

application of clinical tools and evidence-based guidelines. The diagnostic accuracy of the service is supported by low counts of unplanned representations to the ED for patients who are managed by ENPs.

Table 1 Studies included in the literature review

Study	Aims	Service model	Methods	Outcomes studied	Results
Atkinson et al., 2014	To evaluate the accuracy of ENP service in ultrasound detection of soft tissue foreign bodies (FBs)	Ten ENPs who had completed a two-hour training session Trauma centre, USA	FBs inserted into eight experimental models randomly by independent observer. NPs assessed on ability to detect FB	Sensitivity, specificity, positive predictive value and negative predictive value of ENP-performed examinations	Diagnostic accuracy equivalent to emergency physicians.
Carter & Chochinov, 2007	Systematic review	NPs either qualified or in training Comparison with junior doctors Minor injury and illness	36 primary studies were included	Cost Quality of care Satisfaction with care Waiting times	Cost higher for ENP care Quality of care equal to doctors Greater patient satisfaction with ENP service Shorter waiting times for ENP cohort
Colligan et al., 2011	To determine if ENPs were as effective as emergency medicine registrars in managing minor injuries	Two newly qualified ENPs Adults with minor trauma Metropolitan ED in New Zealand	Prospective observational audit – chart audit Non-consecutive patients	LOS Waiting time Left-without-being-seen Unplanned representations Diagnostic accuracy of x-ray interpretation	Waiting time and LOS shorter for patients managed by ENP service. No differences between service models for other outcomes.
Considine et al., 2006	To compare emergency department waiting times, treatment times and length of stay for patients managed by a training ENP service and those managed in the standard model of care.	ENP candidate (single clinician) Minor injury and illness Metropolitan ED in Australia	Case control study Patients selected from three most common ED diagnostic groups: hand/wrist wounds, hand/wrist fractures and removal of plaster casts.	Waiting time Treatment times LOS	No significant differences between service models.
Considine et al., 2010	To examine the effect of clinician designation on emergency department fast track performance.	ENP candidate or qualified ENP Fast track Metropolitan ED in Australia	Retrospective chart audit	Waiting times LOS	Shortest LOS and highest compliance with national waiting time standards for patients of ENP service.
Dewar & Corretge, 2008	To determine inter-observer variability between clinicians for the use of the Wells score	ENP (single clinician) and a single emergency consultant. Patients with suspected diagnosis of deep vein thrombosis.	Prospective cohort study 100 participants with suspected DVT Blinded assessment by each clinician independently.	Wells score	Same final Wells score in 81% of cases (simple agreement), with a kappa score of 0.74 (95% CI 0.63 to 0.84).

Study	Aims	Service model	Methods	Outcomes studied	Results
Dinh et al., 2012	To evaluate the quality of care delivered in an ED fast track unit	ENP (single clinician) compared with standard care. Metropolitan ED in Australia Minor injury and illness	Observational study A convenience sample of adult patients were randomised to care by a doctor or an ENP. Quality of care was measured using patient satisfaction, follow up health status using Short Form 12 and adverse event rate (missed fractures or unplanned representations).	Patient satisfaction Quality-of-life Adverse event rate	High quality of care for patients managed in this fast track unit. Patient satisfaction scores higher for ENP group than for DR group.
Ducharme et al., 2009	To assess the impact of the integration of new roles on organisational outcomes	ENPs or physician assistants. Service provider additional to existing health care team. Very small number of ENPs included in the study	Retrospective case audit Six Canadian EDs	LOS Waiting times Left-without-being seen	Improved patient flow with the introduction of mid-level providers
Feetham et al., 2015	To establish the unplanned representation rate for ENPs and to identify the patient case mix	Four paediatric ENP's compared with either senior or junior doctor led care. Tertiary paediatric ED in the UK.	Retrospective review Convenience sample across two different time periods	Unplanned representations	ENP had a lower re-attendance rate compared to doctors.
Fry et al., 2011	To describe patient characteristics, examine efficiency and safety and evaluate the impact of the "transitional" ENP role.	NPs in training Minor injury and illness Single Australian Metropolitan ED	Prospective observational study Data on patient flow after the implementation of the ENP service was compared to data from the prior 12-months.	Waiting times LOS Left-without-being seen	Improvements in waiting times, LOS and left-without-being-seen were noted compared to the previous year.
Hart & Mirabella, 2009	To determine the willingness of ED fast track patients to be treated by advanced practice nurses.	Fast track patients Three American adult EDs	Descriptive patient survey Convenience sample – low response rate	Willingness to be managed by ENP service	Majority of patients willing to be treated by ENP.
Henderson et al., 2010	To assess the adequacy of NP performed bedside ultrasound investigations	Five ENPs American trauma centre ED	Retrospective audit Review of ENP ultrasound examinations undertaken over a two-month period by emergency physician with specialist ultrasound qualifications.	Adequacy of ultrasound images Accuracy of interpretation of images	Overall, the NPs achieved a sensitivity level of 93% and a specificity level of 98%.

Study	Aims	Service model	Methods	Outcomes studied	Results
Hopkins, 2010	To compare the efficacy of ENPs and doctors in the implementation of the Ottawa ankle rule.	Sample of 15 ENPs and 15 Senior House Officers selected for inclusion. Adult patients with simple foot or ankle injuries	Retrospective audit 60 patients randomly selected from 4800 patients potentially eligible for inclusion	Adherence to evidence-based protocol	Flaws in documentation by both ENPs and SHOs were noted.
Jarvis, 2007	To determine the level of patient satisfaction with the ENP service	Established ENP service in the UK	Self administered patient questionnaire – adapted from a previous survey of ENP service High response rate (85%)	Satisfaction with care	Patients were pleased with all aspects of ENP service, consistently rating it as "excellent" or "very good"
Jeanmonod et al., 2013	To evaluate productivity and compare patient satisfaction for low acuity ED patients	"Mid-level providers" (5 PAs and 1 NP) compared with residents Fast track Tertiary American ED	Retrospective review of clinician productivity Prospective study of patient satisfaction	Satisfaction with care Productivity	Mid-level providers treated more patients per hour than residents. Majority of patients "highly satisfied" with care – no differences between service providers.
Jennings et al., 2008	To evaluate the impact of the introduction of ENPCs on waiting times and length of stay	NPs in training Minor injury and illness Major Australian metropolitan ED	Retrospective case series	Waiting times LOS	Significantly shorter waiting times and LOS for patients managed by ENPC service model
Jennings et al., 2009	To explore satisfaction with care provided by ENPs and ED doctors.	ENP service (including both qualified and training NPs) Minor injury and illness Major Australian metropolitan ED	Prospective patient survey Validated tool using a 16-item Likert Scale	Patient satisfaction	Majority of questions (12/16) demonstrated a significant difference in favour of the ENP service.
Jennings et al., 2013	To obtain a profile of characteristics for patients managed by ENP service	Established ENP service (including both qualified and training NPs) Minor injury and illness Major Australian metropolitan ED	Retrospective review	Patient demographics Waiting times LOS Presentation types Referral patterns	Baseline characteristics and results on service indicators established.
Jennings et al., 2015	Systematic review	Included nurses with varying practice scopes and qualifications Minor injury and illness	Replicated Carter & Chochinov's search strategy 14 studies included – Two systematic reviews, two RCTs and 10 observational studies	Cost Quality of care Satisfaction with care Waiting times	Positive impact on quality of care, patient satisfaction and waiting times. Unable to determine impact of service on cost

Study	Aims	Service model	Methods	Outcomes studied	Results
Jennings et al., 2015	To evaluate time to analgesia for patients with pain managed by ENP service	Established ENP service (including both qualified and training NPs) Minor injury and illness Major Australian metropolitan ED	Retrospective study	Time to analgesia	Majority of patients assessed by ENP were administered analgesia within 30-minutes.
Jennings et al., 2015a	To evaluate the effectiveness of ENP service on clinical patient outcomes and key service indicators.	Established ENP service Minor injury and illness Major Australian metropolitan ED Comparison with emergency registrars	RCT	Waiting times LOS Unplanned representations Left-without-being-seen	No differences between groups for any outcome.
Jennings et al., 2015b	To evaluate the effect of ENP service on time to analgesia	Established ENP service Minor injury and illness Major Australian metropolitan ED Comparison with emergency registrars	RCT	Time to analgesia	Higher proportion of patients in the ENP group than in the standard care group (49.2% vs 29.7%) received analgesia within 30 minutes
Lau et al., 2013	To compare assessment of suspected ankle and foot injuries using the Ottawa Ankle Rule by ENP service and standard care	Major Australian metropolitan ED ENP service compared to doctors	Prospective observational study	Adherence to evidence-based protocol Diagnostic accuracy of x-ray interpretation	ENPs less likely to miss clinically significant fractures compared with doctors
Lee et al., 2014	To compare the accuracy in interpreting isolated adult limb radiographs between emergency nurse practitioners and emergency physicians.	ENPs and consultant emergency physicians Comparison with findings of consultant radiologist Adults with isolated limb injuries	Single centre Australian tertiary ED	Diagnostic accuracy of x-ray interpretation	The sensitivity for the ENP service was 91% and 88% for the emergency physicians. The specificity for the ENP service was 85% and for the emergency physicians 91%.
Lutze et al., 2011	The aim of the study was to explore the ENP model, describe the demographic characteristics of the ENP patient cohort and examine the safety and quality of the service.	Transitional ENP model (ENPs in training) Single practitioner across both sites.	Two Australian urban EDs Retrospective exploratory study.	Patient flow Patient complaints Unplanned representations Appropriateness of diagnostic investigations	The TENP service limited to ATS 4 and 5 patients. Large number of presentations managed were planned reviews. No unplanned representations, patient complaints. Appropriate use of diagnostic investigations.

Study	Aims	Service model	Methods	Outcomes studied	Results
Lutze et al., 2013	To compare patient satisfaction between ENP service and standard care	Two models of care • Tertiary ED staffed by doctors • Urban hospital staffed by ENPs	Australian study Observational study using convenience sample Patient satisfaction survey	Satisfaction with care	86% of patients rated care as "excellent" or "very good" Satisfaction scores in the ENP group were higher than those in the DR group (median score 4 vs. 3, $p < 0.01$)
McDevitt & Melby, 2015	To evaluate the quality of the ENP service rural urgent care centre	Minor injury and illness Nurse led urgent care centre Rural UK hospital	Descriptive study Retrospective case note review Validated patient survey	Satisfaction with care Unplanned representations Organisational indicators	97.3% felt care was of a high standard Unplanned representations 3.6%; mean waiting time 22 mins; LOS 45 mins
McGoldrick et al., 2011	To assess the appropriateness of ENP referrals to specialist clinic.	Not described	Referrals of patients to a tertiary hand trauma service Prospective study of 100 patients attending trauma clinic	Quality of referral	No significant differences in the quality of referral between ENPs and doctors.
Nash et al., 2007	To assess the efficiency of a newly created Fast Track Unit	Fast track unit staffed by ENPs American university affiliated hospital Minor injury and illness	Exploratory descriptive study Retrospective chart review Prospective patient survey	Satisfaction with care Left-without-being-seen Unplanned representations	100% of patients rated care as "good" or "excellent" Shorter LOS and lower rate of LWBS than main ED
Pirret et al., 2015	To compare the diagnostic reasoning abilities of NPs and medical registrars	NPs (n=30) and doctors (n=16) working in multiple clinical specialities New Zealand study	Complex case scenario	Correct diagnoses, problems and actions (as determined by an expert panel)	NP diagnostic reasoning abilities compared well with doctors
Sanhu et al., 2009	To compare consultation length and content; patient satisfaction and clinician satisfaction with the consultation.	ENPs (n=6) and doctors (n=29) of varying experience Inner city UK hospital Minor injury and illness	Videotaped consultations coded for themes Validated patient satisfaction questionnaire	Satisfaction with care Consultation length Clinician satisfaction	ENPs and GPs focused more on patient education and counselling than ED doctors. No significant differences in consultation length. ENPs had higher levels of overall self-satisfaction than ED doctors.

Study	Aims	Service model	Methods	Outcomes studied	Results
Steiner et al., 2009	To determine if ENP service could improve waiting times, length-of-stay and left-without-being-seen rates	NP service model Emergency physician retained ultimate decision making authority ENP autonomous practice limited to specific patient cohort Minor injury and illness	Prospective observational study Compared differences during shifts when ENP was rostered to shifts without ENP service ENP service was additional to the existing health care team	LOS Waiting times Left-without-being seen	12% increase in patient volume per shift 7% reduction in mean wait times Lower proportion of LWBS (11.9% vs 13.7%, p=0.10)
Thompson & Meskell, 2012	To compare ENP service to standard medical care in the management of minor injury and illness presentations	General hospital ED in Ireland Minor injury and illness	Retrospective audit	LOS Diagnostic accuracy of x-ray interpretation	ENP lowest rate of false negatives ENP false positive rates lower than for all grades of medical officer except consultant Average wait time 51 mins for ENP and consultant cohort; longer for all other cohorts
Thrasher & Purc-Stephenson, 2008	To develop a valid and reliable measure of patient satisfaction in order to identify various components of patient satisfaction with ENP care	6 EDs in Canada selected from a sample of 18 EDs that were chosen to ensure broad representation of different types of EDs	21-item self-administered patient survey that used Likert scale Measured “Attentiveness”, “Comprehensiveness” and “Role Clarity”	Satisfaction with care	71% preferred to see the ENP rather than a doctor Highly satisfied with care Moderate understanding of the role
Tsai et al., 2010	To evaluate the quality of care provided by either ENPs or physician assistants to patients with asthma	“Mid-level providers” (MLPs); a group that combined patients managed by physician assistants and ENPs. Only 0.66% of the total sample were managed by ENP service. Adult patients with asthma	Retrospective multicentre study 63 Urban EDs in the USA	Adherence to evidence-based guidelines Outcomes of care – LOS and disposition	Unsupervised MLPs were less likely to adhere to guidelines compared with physicians or supervised MLPs Unsupervised MLP patient cohort had a shorter LOS and were less likely to be admitted, as compared with patients cared for by physicians or supervised MLPs.

Study	Aims	Service model	Methods	Outcomes studied	Results
van der Linden et al., 2010	To determine the incidence of missed injuries and to evaluate diagnostic accuracy of ENP service model	Comparison of ENP care with junior doctors and senior house officers Minor injury and illness	Retrospective cohort study	Diagnostic accuracy - missed injury rate	ENPs have high diagnostic accuracy (97.3% of patients correctly diagnosed and managed) No difference between the ENP and physician groups in terms of missed injuries No difference in waiting time between service models.
Wilson et al., 2008	To evaluate the effectiveness of ENP care and explore patient satisfaction with care.	Minor injury and illness Australian metropolitan ED	Retrospective cohort study Case note review Patient survey	Satisfaction with care	91.3% of patients satisfied with overall care
Wilson et al., 2009	Systematic review	NPs either qualified or in training Comparison with junior doctors Minor injury and illness	9 primary studies included	Waiting times Referrals Unplanned representations Cost effectiveness Satisfaction with care	No differences between effectiveness of care provided by ENP service or doctors.
Wood et al., 2007	To determine if use of ENP service for procedural sedation and analgesia (PSA) compared with physicians decreased overall length of stay (LOS)	Paediatric ED Minor injury and illness	Retrospective case review	LOS Time to sedation	Both LOS and time to sedation were lower for ENPs versus doctors ($p>0.01$).

2.3 RISK STRATIFICATION TOOLS FOR PATIENTS WITH CHEST PAIN

This research is focused on the effectiveness of ENPs in managing patients presenting with chest pain in rural ED settings. Review of the literature detailing the management of patients presenting to EDs with chest pain uncovers an abundance of research that has underscored the importance of risk stratification. As detailed in the previous Chapter, nurse practitioners possess complex decision-making skills with legislated extensions for expanded practice including diagnosis, prescribing and referral of patients. The use of risk stratification tools for patients with chest pain is imperative to effective ENP service. In the assessment of patients with chest pain, the emphasis for ED clinicians is not only to rapidly diagnose ACS, but also to exclude this condition and other high-risk conditions that may lead to injury or death. Whilst there is no single or combination of clinical features that can be used to exclude ACS, diagnostic strategies are centred on clinical assessment, ECG interpretation and cardiac biomarker testing (Parsonage et al., 2013). A missed diagnosis of ACS may result in a delay in initiating the appropriate treatment and thereby increasing mortality rates (Schull, Vermeulen, & Stukel, 2006). In 2000, the National Heart Foundation and Cardiac Society of Australia and New Zealand developed guidelines ("Management of unstable angina: Guidelines 2000", 2000) for the management of patients experiencing chest pain. These guidelines were subsequently updated in 2006 (The Cardiac Society of Australia and New Zealand Acute Coronary Syndrome Guidelines Working Group & National Heart Foundation of Australia, 2006) and again in 2011 (Chew, Aroney, Aylward, Kelly, & White, 2011) in alignment with the then current evidence. The guidelines risk stratify patients and outline the process of assessment and management for patients with suspected ACS. The recommendations include ECG and cardiac troponin testing for patients on arrival to ED and again at least six hours later. In addition, for patients with normal serial ECG and troponin measurements, the guidelines recommend provocative testing such as exercise stress tests or myocardial perfusion scans to exclude underlying coronary artery disease and ACS. Although not formally reported previously, due to the requirement for provocative testing that is not possible in resource poor rural EDs, patients are often discharged after a period of observation with outpatient referral for provocative testing.

Clearly then there is a need for an assessment tool which rapidly identifies at high risk of ACS (to enable early definitive treatment) patients and those at low risk who may not require the current guideline recommended extensive assessment processes (whom it would be safe to manage as outpatients). Ideally, a risk stratification tool for patients presenting to rural EDs with chest pain would identify high numbers of patients who can be safely discharged without experiencing ACS in the following 30-days to allow time for outpatient investigation and management. Recently, there has been a plethora of risk stratification tools and accelerated assessment processes that have been reported in the literature (Antman, et al., 2000; Goldman, Cook, Johnson, & et al, 1996; Grace investigators, 2001; Hess, Brison, Perry, et al., 2012; Scheuermeyer, Wong, Yu, et al., 2014; Six, Backus, & Kelder, 2008; Than, Flaws, & Sanders, 2014; The Cardiac Society of Australia and New Zealand Acute Coronary Syndrome Guidelines Working Group & National Heart Foundation of Australia, 2006).

This study provided groundwork for the subsequent research by establishing knowledge of the processes of care and highlighted the significance of risk stratification strategies for patients presenting to rural EDs with chest pain. The use of the current clinical guideline for the management of patients with suspected or confirmed ACS (Chew et al., 2011) necessitated a high proportion of patients being admitted for further observation and management.

The applicability and performance of these tools for use in the cohort of patients presenting to the rural ED with chest pain has not been evaluated previously.

Pursuing this further, a comprehensive evaluation of risk stratification tools with the goal of identify a safe and effective strategy that could be implemented into rural EDs was conducted.

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In the case of this chapter:

Diagnostic accuracy of risk stratification tools for patients with chest pain in the rural emergency department: a systematic review
Article first published online: 30 July 2016

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2.3.1 Publication – Systematic Review

Emergency Medicine Australasia (2016) ••, ••–••

doi: 10.1111/1742-6723.12622

REVIEW ARTICLE

Review article: Diagnostic accuracy of risk stratification tools for patients with chest pain in the rural emergency department: A systematic review

Diagnostic accuracy of risk stratification tools for patients with chest pain in the rural emergency department: a systematic review.

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Article first published online: 30 July 2016

DOI 10.1111/1742-6723.12622

Emergency medicine Australasia

Journal Metrics	
Impact factor	1.296
H index	35
SCImago Journal Rank (SJR)	0.499 

Abstract

Risk stratification tools for patients presenting to rural emergency departments with undifferentiated chest pain enable early definitive treatment in high-risk patients. This systematic review compares the most commonly used risk stratification tools used to predict the risk of Major Adverse Cardiac Event (MACE) for patients presenting to rural emergency departments with chest pain.

A comprehensive search of MEDLINE and Embase for studies published between January 2011 and January 2015 was undertaken. Study quality was assessed using QUADAS-2 criteria and the PRISMA guidelines.

Eleven studies using eight risk stratification tools met the inclusion criteria. The percentage of MACE in the patients stratified as suitable for discharge and the percentage of patients whose scores would have recommended admission that did not experience a MACE event were used as comparisons.

Using the findings of a survey of emergency physicians that found a 1% MACE rate acceptable in discharged patients, the EDACS-ADP was considered the best performer. EDACS-ADP had one of the lowest rates of MACE in those discharged (3/1148, 0.3%) and discharged one of the highest percentage of patients (44.5%). Only the GRACE tool discharged more patients (69% -all patients with scores <100) but had a MACE rate of 4.3% in discharged patients. The HFA/CSANZ guidelines achieved zero cases of MACE but discharged only 1.3% of patients.

EDACS-ADP can potentially increase diagnostic efficiency of patients presenting at ED with chest pain. Further assessment of tool in a rural context, is recommended.

Background

In an era of increasing health service demand (Parsonage et al., 2013), clinical evaluation of patients presenting to emergency departments (ED) is challenging. Patients particularly vulnerable are those with chest pain that require rapid evaluation to identify life-threatening conditions as opposed to benign conditions. Chest pain is symptomatic of many presenting aetiologies, one of which is acute coronary syndrome (ACS). Although the proportion of patients with chest pain who receive a final diagnosis of ACS is small (11.1%) (Cullen, Greenslade, Merollini, et al., 2015), current guidelines for patients with suspected ACS recommend observation and investigations to minimise the risk of major adverse cardiac events (MACE). The morbidity, mortality and economic costs associated with assessment and evaluation of patient presentations with chest pain constitute a significant burden to the Australian health care system (Begg et al., 2007), especially in rural areas.

In rural areas, chest pain accounts for 3.5% of total emergency department (ED) presentations (Roche, Gardner, & Lewis, 2014). The challenge for rural clinicians is balancing risk and resources to determine an appropriate pathway of care and ED disposition. Assessments are required to determine those who are suitable for discharge and those who require early management and referral. Limited access to services including functional testing and invasive treatments in rural areas leads to an increased need for interfacility transfer, with a resultant impact on staff, resources, healthcare costs and patient safely. Patient transfers also result in significant delays in providing definitive care, particularly in rural communities. Rural communities in Australia are often characterised by geographical isolation combined with typically smaller health services and poorer access to advanced medical facilities in major metropolitan areas. As such, rural patients are at increased risk of adverse outcome from ACS due to distance and associated travel times (Australian Institute of Health and Welfare, 2011, 2014b). Commonly, transferring patients between healthcare facilities requires the use of fully equipped and staffed ambulances – the same ambulances that are used to respond to emergencies within the community. The risk of transfer (both to the patient and the whole community) needs to be balanced against the expected benefits of treatment. The ability of rural clinicians to accurately evaluate and determine which patient is

likely to have ACS and require transfer for treatment compared to those that can be safely discharged for testing as an outpatient is crucial in the clinical process.

The initial evaluation and management of a patient with undifferentiated chest pain requires clinical assessment with physical assessment, electrocardiograph (ECG), cardiac biomarkers and risk stratification (Amsterdam, et al, 2014). Currently, several risk stratification tools or scores for predicting acute coronary syndrome are described in the contemporary literature and widely used in clinical practice. A number of studies have compared the discriminatory performance of TIMI, GRACE and alternative risk scores (Backus, et al, 2011; D'Ascenzo, Biondi-Zoccai, Moretti et al, 2012; Yan et al., 2007) for patients diagnosed with acute coronary syndrome however, no study has compared the performance of risk stratification tools for the cohort of patients presenting to ED with undifferentiated chest pain. Our objective was to compare the diagnostic test accuracy of risk stratification tools/scores for predicting major adverse cardiac events in people presenting to rural EDs with undifferentiated chest pain.

Methods

The systematic review design conforms to the recommendations from the Meta-analysis of Observational Studies in Epidemiology (MOOSE) statement and Preferred Reporting of Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher, Liberati, Altman, et al., 2009; Stroup, et al., 2000).

Eligibility criteria

All diagnostic accuracy studies that compared one or more of the risk stratification tools in patients presenting to EDs with undifferentiated chest pain were included. These studies evaluated the risk stratification tools in the prediction of major adverse cardiac events (MACE). The review included only results from full reports of prospective studies. Studies that used health technologies (in the determination of the risk score) that are not readily available in the rural setting (for example coronary angiography) and specialised cardiac biomarkers that require central laboratory testing were also excluded. Specifically, our review included only those studies that used troponin to allow replication in the rural setting where reliance is on point of care testing. For studies reported in multiple publications, only the most recent or complete reports were included.

Target condition being diagnosed

The target condition was major adverse cardiac events (MACE) in patients presenting to EDs with undifferentiated chest pain. MACE included death, cardiac arrest, revascularization, cardiogenic shock, arrhythmia and prevalent (cause of presentation) and incident (occurring within the follow-up period) myocardial infarction.

Index tests

The review identified several risk stratification tools used in the evaluation of patients presenting to EDs with undifferentiated chest pain (see Table 2): (i) Thrombolysis in Myocardial Infarction Score (TIMI), (ii) Global Registry of Acute Coronary Events score (GRACE), (iii) Cardiac Society of Australia and New Zealand/ National Heart Foundation (CSANZ/NHF) guidelines, (iv) Vancouver chest pain rule, (v) North American Chest Pain Rule (NACPR), (vi) History, ECG, Age, Risk Factors & Troponin (HEART) score, (vii) Emergency Department Assessment of Chest pain Score (EDACS), and (viii) the Goldman risk score.

Search methods for identification of studies

The search strategy included using MEDLINE, EMBASE, E-Journals, Academic Search Elite, CINAHL and the Cochrane Register of Diagnostic Test Accuracy Studies. A three-step search strategy for the concepts of ED setting, risk stratification tools/scores and chest pain were utilised. These strategies were established using a combination of standardised terms and keywords. Initial keyword terms used were combined to yield our search results. A librarian assisted with the search strategy using the MeSH terms and keywords, adapted to suit the needs of each of the databases searched. All searches were completed in January 2015 and limited to those published in English since 2011 using database-supplied limits. All results were exported into EndNote. The automatic duplicate finder in EndNote identified 65 duplicates (which were removed) leaving a total of 508 unique citations. See Appendix A for the MEDLINE search strategy. Reference lists of articles selected were also searched for other relevant primary diagnostic studies and systematic reviews not already located.

Study selection

Two review authors independently screened the titles and abstracts of retrieved records to identify potentially relevant studies for inclusion. Studies which did not meet the inclusion criteria were excluded, and copies of the full text of potentially relevant studies were obtained. The authors independently assessed the full text articles and determined inclusion or exclusion of the studies. Any uncertainties or disagreements were resolved by discussion and agreed by consensus.

Data collection process

Two other review authors independently collected the available data using a data extraction form without masking of study authors or other identifying information. A third review author was consulted for resolution of any disagreements. The following data were retrieved: (i) general information: title, journal, year, location of study; (ii) sample size: number of participants and number lost to follow-up; (iii) baseline characteristics: age, gender; (iv) definition of myocardial infarction used; (v) risk stratification score/tool used; (vi) definition of MACE used, duration and method of follow-up; and, (vii) number of patients with MACE or without MACE. The authors extracted the data from each study for each score/tool. No data were excluded for any category of the studies.

Assessment of methodological quality

The methodological quality of the included studies was assessed independently by two review authors and disagreement on study quality was resolved by a third reviewer. Where necessary, requests to primary study authors for additional information or clarification was directed. The methodological quality of studies was assessed using a modified version of the *QUality Assessment of Diagnostic Accuracy Studies* (QUADAS-2) tool (Whiting, Tutjes, Westwood et al. 2011). The QUADAS-2 tool assesses quality in four domains including patient selection, index test, reference standard, flow and timing. The standardised checklist included 11 criteria to rate the risk of bias and the applicability of the study to the research question by indicating a "low", "high" or "unclear" rating. In order to have an overall judgment of "low risk of bias" or "low concern regarding applicability", a study must be ranked as "low" on all relevant domains. If a study receives a "high" or "unclear"

Table 2 Risk stratification tools and treatment recommendations by risk category for studies included in the review

Risk tool	Risk Category and Treatment Recommendations	Features
i) Thrombolysis in Myocardial Infarction Score (Antman, et al., 2000)	No recommendations provided on ongoing management for patients with undifferentiated chest pain presenting to emergency departments. Many guidelines recommend higher scoring patients receive more aggressive medical intervention and/or early invasive management.	1 point for each positive risk factor • Age >65 years • Prior coronary artery stenosis>50% or prior PCI or CABG or prior AMI • 3 or more cardiac risk factors (hypertension, diabetes, dyslipidaemia, family history, smoker) • Use of aspirin in the preceding 7 days • 2 or more angina events in the past 24 hours • ST-segment elevation or depression >1mm • Elevated cardiac biomarkers
ii) Global Registry of Acute Cardiac Events (GRACE) score (Grace Investigators, 2001; Tang, Wong, & Herbision, 2007)	No recommendations provided for ongoing management for patients with undifferentiated chest pain presenting to emergency departments	Scores predictor variables including: • Age, • Heart rate (HR), • Systolic blood pressure (SBP), • Creatinine level, • Killip class of heart failure, • Cardiac arrest at admission, • ST-segment deviation, and • cardiac enzymes
iii) National Heart Foundation / Cardiac Society of Australia and New Zealand (NHF/CSANZ) guidelines (The Cardiac Society of Australia and New Zealand Acute Coronary Syndrome Guidelines Working Group & National Heart Foundation of Australia, 2006)	High risk→aggressive medical management & early invasive strategy	Presentation with clinical features consistent with ACS and any of: • Repetitive or prolonged (>10 mins) ongoing chest pain/discomfort • Elevation of at least one cardiac biomarker • Persistent or dynamic ST depression or new T wave inversion • Transient ST elevation in more than 2 contiguous leads • Haemodynamic compromise • Sustained VT or syncope • Left ventricular dysfunction • Prior PCI within 6 months or prior CABG • Presence of diabetes or chronic kidney disease with typical symptoms of ACS
	Intermediate risk→accelerated diagnostic evaluation and further assessment to allow reclassification as low or high risk	Presentation with clinical features consistent with ACS and any of: • Chest pain or discomfort within the past 48 hours (but currently resolved) • Age >65 years • Known coronary artery disease • No high-risk ECG changes • Two or more of: hypertension, family history, active smoking, hyperlipidaemia • Presence of diabetes or chronic kidney disease with atypical symptoms of ACS • Prior aspirin use **AND NOT** meeting the criteria for high-risk NSTEACS
	Low risk→Discharge after observation and assessment	Presentation with clinical features consistent with ACS without intermediate- or high-risk features

Risk tool	Risk Category and Treatment Recommendations	Features		
iv) Vancouver chest pain rule (Scheuermeyer, Wong, Yu et al., 2014)	Patient may be discharged without further testing if **NONE** of the criteria are met	The patient is low-risk and suitable for early discharge if all questions are answered "No": **Step 1** • Abnormal initial ECG • Positive troponin at 2-hours • Prior ACS or nitrate use **Step 2** • Does palpation reproduce pain? If pain is reproducible, patient is suitable for early discharge and does not require Step 3 questions. **Step 3** • Age 50 and above? • Does pain radiate to neck, jaw, or left arm?		
v) North American Chest Pain Rule (NACPR) (Hess, Brison, Perry et al., 2012)	Patient may be discharged without further testing if **NONE** of the criteria are met	• New ischaemia on ECG • History of coronary artery disease • Pain is typical for ACS • Initial troponin is negative **AND** • Age ≤ 40 years **OR** • Age 41-50 years and repeat troponin at least 6-hours from symptom onset is negative		
vi) History, ECG, Age, Risk factors and Troponin (HEART) score (Six et al., 2008)	Score 0 – 3→Discharge home Score 4 – 6 →Admit for clinical observation Score 7 – 10→Early invasive strategy	History	Highly suspicious Moderately suspicious Slightly suspicious	2 points 1 point 0 points
		ECG	Significant ST Depression Nonspecific repolarization Normal	2 points 1 point 0 points
		Age	≥ 65 years > 45 - < 65 years ≤ 45 years	2 points 1 point 0 points
		Risk Factors	≥ 3 risk factors or history of CAD 1 or 2 risk factors No risk factors	2 points 1 point 0 points
		Troponin	≥ 3 x normal limit > 1 - < 3 x normal limit ≤ Normal limit	2 points 1 point 0 points

Risk tool	Risk Category and Treatment Recommendations	Features
vii) Emergency Department Assessment of Chest Pain Score (EDACS) (Than et al., 2014)	Low Risk Cohort: • EDACS < 16 and • If ECG shows no new ischemia and • 0h and 2h troponin both negative → Discharge home	Scores predictor variables including: • Age • Sex • Known coronary artery disease or ≥ 3 risk factors • Diaphoresis • Radiates to arm or shoulder • Pain occurred or worsened with inspiration • Pain is reproduced by palpation
	Not Low Risk Cohort: • EDACS ≥16 or • ECG shows new ischemia • 0h or 2h troponin positive • Abnormal vital signs • Pain that is ongoing or in a crescendo pattern →Admit for clinical observation	
viii) Goldman risk score (Goldman, Cook, Johnson et al., 1996)	Very low risk	No ECG evidence of ACS **AND NONE** of the following urgent factors: • Rales above both lung bases • Systolic BP <100 mmHg • Unstable IHD
	Low risk	No ECG evidence of ACS and 1 of the urgent factors
	Moderate risk	No ECG evidence of ACS and 2 or 3 of the urgent factors **OR** ECG evidence of ACS and 0 or 1 of the urgent factors
	High risk	ECG evidence of AMI alone or ECG evidence of acute ischaemia with 2 or 3 of the urgent factors

rating in one or more domains, then it may be judged as "at risk of bias" or having "concerns regarding applicability".

Statistical analysis and data synthesis

Extracted data were used to create tables describing the percentage of patients eligible for discharge based on individual tool assessments, the observed percentage of MACE in the discharged population and the percentage of patients who should have been admitted or transferred according to the tool criteria, but did not have an episode of MACE within thirty days of presentation.

Results

Results of the search

The search strategy identified 573 references and one additional record identified through other sources. Of these, 536 were excluded by initial screening of reference titles and abstracts. There were 65 duplicates and 471 were either not relevant or did not meet inclusion criteria. Full text reports were obtained for the 37 potentially eligible studies that were remaining, 17 of these met the inclusion criteria and were included in the review. The PRISMA (Moher et al., 2009) flow diagram has been utilized to demonstrate the flow of information through the different phases of the review (Figure 2). No study that evaluated the effectiveness of risk stratification tools for the cohort of patients presenting with undifferentiated chest pain to rural facilities was identified.

Methodological quality of the identified studies

Using the modified QUADAS-2 tool, the methodological quality of the 17 included studies was judged to be high for most domains. The main results are summarized below (Figure 3; Figure 4).

In the patient selection domain four studies were judged (Holly, 2013; Kelly, 2012a; Macdonald, 2011; Macdonald, 2014) to be at high risk of bias due to patient sampling methods and inclusion criteria. The remaining 13 studies were considered to be at low risk of bias. For patient selection to be considered at low risk of bias and at low concern regarding applicability, studies had to be prospective with a consecutive or random recruitment of patients within the emergency setting presenting with undifferentiated chest pain. Many studies did not provide enough

information about independence and blinding between the calculation of the risk score and the final diagnosis of MACE. Where appropriate, the corresponding author was contacted to confirm that blinding had occurred (Burkett, Marwick, Thom & Kelly, 2014; Cullen, 2013; Graham, 2014; Than, 2012; Than, 2014). In the index test domain three studies (Kelly, 2012a; Kelly, 2012b; Macdonald, 2011) were considered to have an unclear risk of bias because there was no reporting as to whether determination of the risk score by clinicians occurred without knowledge of patient outcome. The remaining 14 studies were judged to be at low risk of bias. Similarly, in the reference test domain an absence of reporting of blinding of the risk score in the determination of patient outcome led to three studies (Aldous, 2012; Kelly, 2012a; Macdonald, 2011) having an unclear risk of bias. A single study (Kelly, 2012b) was considered at high risk of bias because of an unclear MACE definition and heterogeneity. All other studies were considered to be at low risk of bias in the reference standard domain.

In the flow and timing domain the majority of studies (n = 15) were considered to be at low risk of bias. One study (Holly, 2013) was judged to be at high risk of bias and one (Kelly, 2012b) to be at unclear risk of bias due to losses to follow-up (greater than 10%) or poor reporting of timing of follow-up, or both.

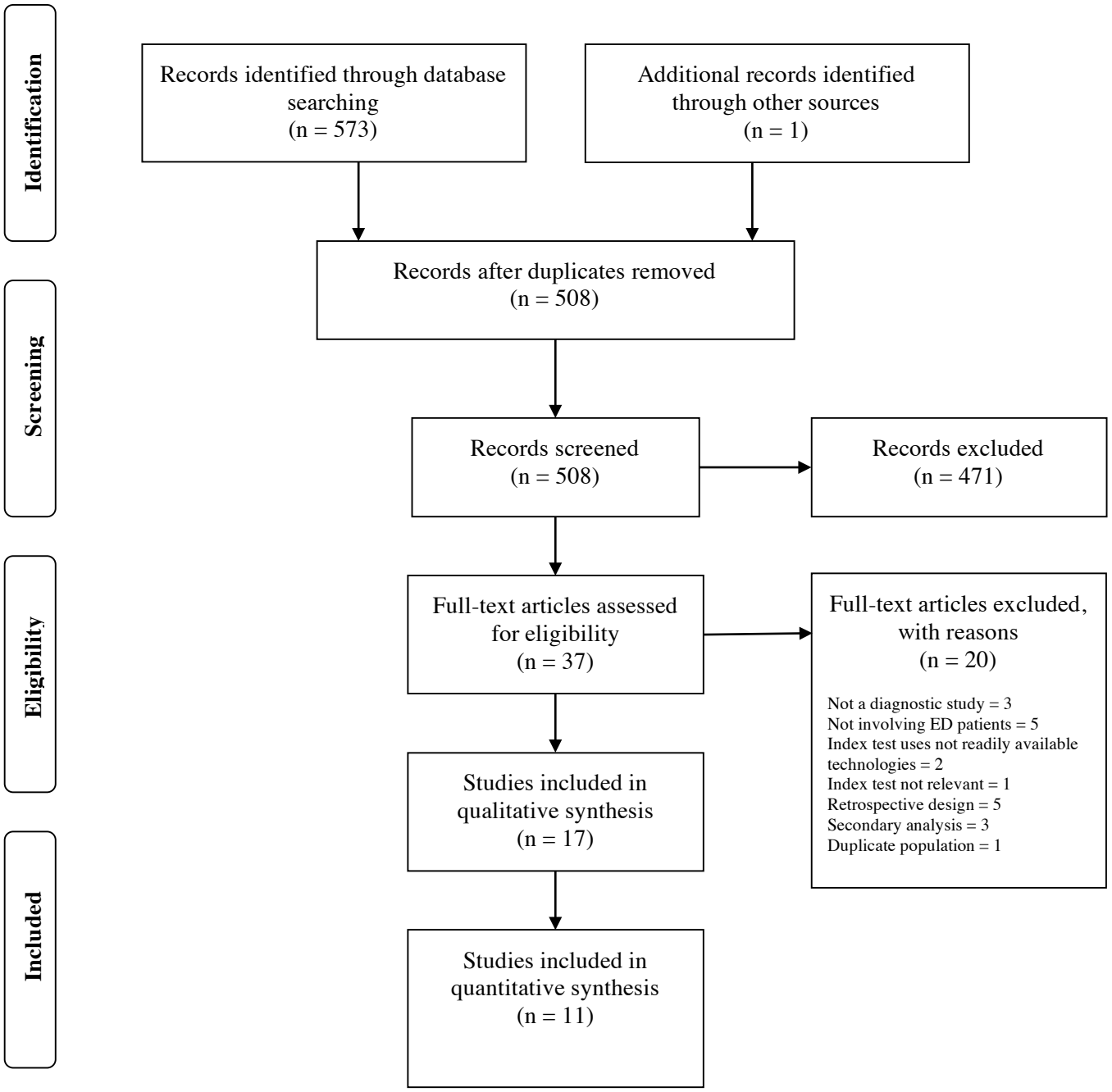

Figure 2 Flow diagram of the study selection process

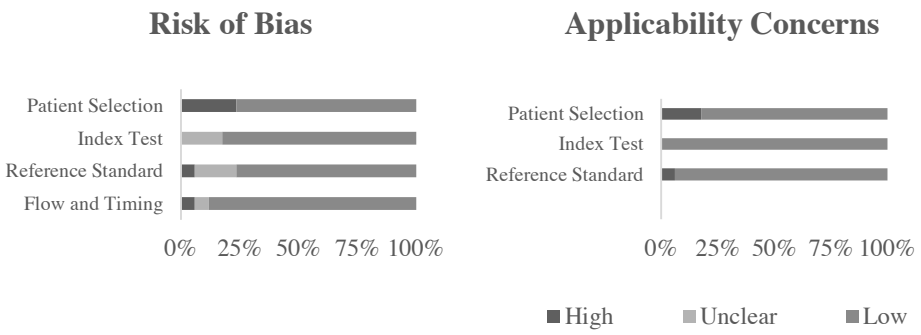

Figure 3 Risk of bias and applicability concerns summary: review authors' judgments about each domain presented as percentages across all included studies

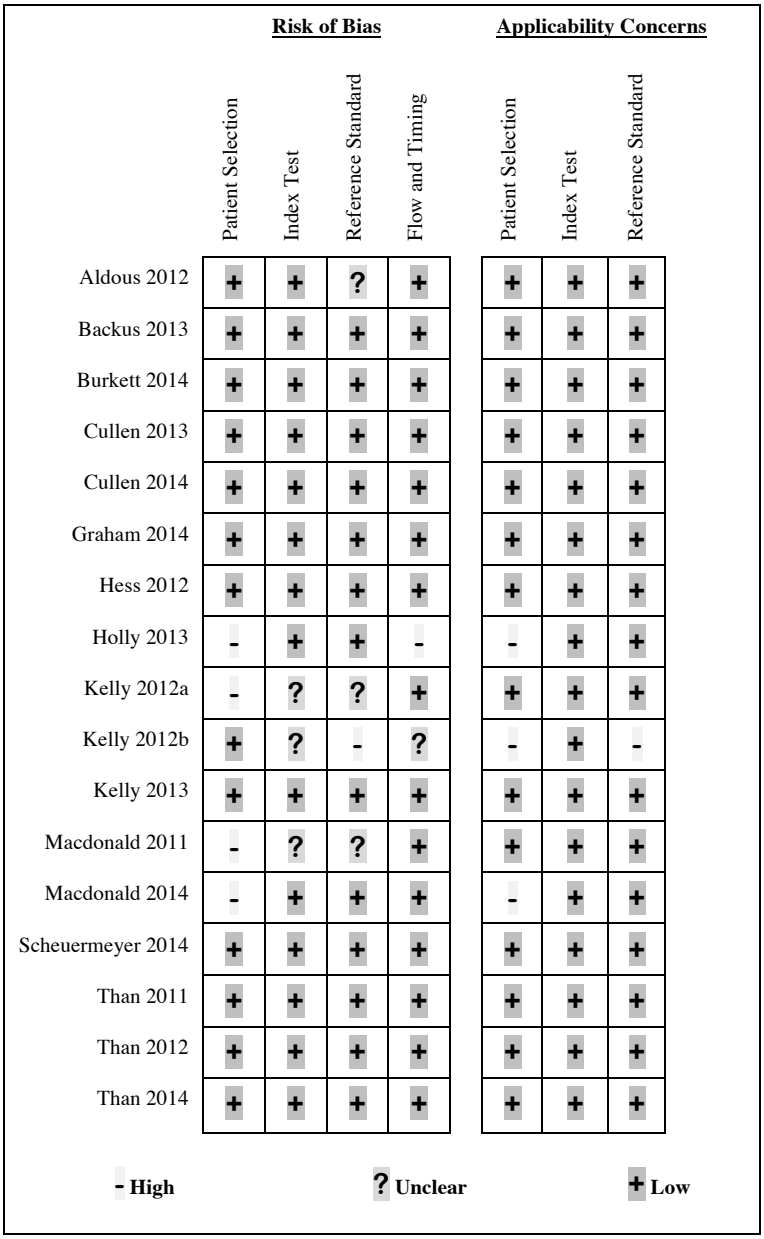

Figure 4 Risk of bias and applicability concerns summary: review authors' judgments about each domain for each included study

For assessment of applicability concerns, for the majority of the studies (n =14) there was no concern that the included patients and setting, conduct and interpretation of the risk score/tool, and the target condition (MACE) did not match the review question. It was judged that there was high concern about applicability for Holly 2013, Kelly 2012b and Macdonald 2014 regarding the patient selection domain because included patients did not match the review question (undifferentiated chest pain presentations) and Kelly 2012b regarding the reference standard domain (target condition not matching the review question).

Using this assessment of methodological quality, six studies were excluded from further analysis for this review: Aldous 2012, Holly 2013, Kelly 2012a, Kelly 2012b, Macdonald 2011 and Macdonald 2014.

Findings

Included studies are detailed in Table 3. The total number of participants across all included studies was 17,553 of whom 2,733 (15.6%) experienced a MACE at follow-up.

In the eleven studies identified, eight different risk scores were utilised. Burkett 2014, Backus 2013 and Cullen 2013 assessed three tools each, Graham 2014 assessed two variants of TIMI, Cullen 2014 assessed one tool but compared two variants of troponin analysis. All other studies assessed one tool only. Those studies that compared multiple tools utilised the same patients for each tool. There were also three accelerated diagnostic protocols (ADPs) included in the review. Than 2011 and Than 2012 used a protocol that incorporated TIMI and Than 2014 used EDACS in the determination of risk. Table 4 shows the distribution of tools against studies. The authors that reported TIMI, chose to collapse and report the scores in slightly different ways, which limited the data that could be extracted and combined, but some studies published sufficient detail to allow experimentation with varying discharge criteria.

Statistical analysis and data synthesis

A meta analysis was planned, but was not considered to be relevant to the research question, which was to compare tools, not to compare studies using the same tool. Furthermore, few tools were represented by more than one study, and not

Table 3 Characteristics of the studies included in the quantitative review of risk stratification instruments to predict the short-term risk of major adverse cardiac events (MACE)

Study	**Location**	**No. of participants**	**No. (%) of men**	**Age**	**Definition of myocardial infarction used**	**Definition of MACE used**	**Duration and method of follow-up**	**Risk stratification instrument used** **Index test**	**No. (%) lost to follow up**	**No. (%) of patients with cardiac events**
Backus 2013	10 EDs; 3 tertiary, rest urban Netherlands	2 440	1372 (57.5)	60 (SD 15.4)	Universal	AMI, revascularization, coronary angiography revealing coronary stenosis managed conservatively, death (all causes).	6-weeks; MRR, phone follow-up	HEART score **External validation**	52 (2.1)	407 (16.7)
Burkett 2014	Tertiary ED Australia	281	173 (61.5)	56 (IQR 47.5-66)	ACC criteria	AMI, revascularization, cardiogenic shock, arrhythmia or atrioventricular block requiring intervention, cardiac arrest or death (all causes)	72 hrs and 30-day†; MRR, phone follow-up	HFA/CSANZ Goldman risk score TIMI risk score **External validation**	5 (1.78)	39 (14.1)
Cullen 2013	Tertiary ED Australia	948	568 (59.9)	54 (IQR 44-64)	Universal	Death (unless clearly non-cardiac), AMI and unstable angina.	30-day; phone follow-up, review of National Death Index	HFA/CSANZ TIMI risk score GRACE **External validation**	0	91 (9.6)
Cullen 2014	2 tertiary EDs Australia & New Zealand	1 635	976 (59.7)	60 (IQR 50-72)	Universal	ACS including AMI and unstable angina	30-day; MMR	Vancouver Score **External validation** *Plus either* hsTnI *or* cTnI	0	334 (20.4)
Graham 2014	University hospital Hong Kong	925	478 (51.7)	68 (IQR 56-78)	ACC criteria	Death (all causes), revascularization, AMI	30-day; MRR, phone follow-up	TIMI risk score Front door TIMI risk score **External validation**	0	119 (12.9)
Hess 2012	3 academic EDs Canada	2 718	1 439 (52.9)	60 (SD 14.9)	Elevated troponin, ECG changes	AMI, revascularization, death (all causes)	30-day; phone follow-up; MRR, review of coroner's database	NACPR **Derivation study**	0	336 (12)

Study	Location	No. of participants	No. (%) of men	Age	Definition of myocardial infarction used	Definition of MACE used	Duration and method of follow-up	Risk stratification instrument used Index test	No. (%) lost to follow up	No. (%) of patients with cardiac events
Kelly 2013	Community teaching hospital Australia	651	376 (57.8)	Low risk 44 (IQR 42-46) Higher risk 65 (IQR 63-66)	Not available	Death (unless clearly non-cardiac), cardiac arrest, revascularization, cardiogenic shock, arrhythmia requiring intervention, AMI	7- and 30-day; phone follow-up[†]	ADP **(uses TIMI score)** **Derivation study**	3[#] (0.5)	95[#] (14.6)
Scheuermeyer 2014	Tertiary ED Canada	Derivation 782 Validation 960	473 (62) 555 (61.2)	58 (SD 14) 60 (SD 15)	Elevated cardiac biomarkers ECG changes	ACS including AMI and unstable angina	30-day; phone follow-up, death and national hospital registry check	Vancouver risk score **Derivation study** **Internal validation study**	19 (2.4) 54 (5.6)	165 (21.6) 119 (13.1)
Than 2011	14 EDs; tertiary to urban 9 countries in Asia-Pacific region	3 630	2 234 (62.4)	61.5 (SD 14.1)	Universal	Death (unless clearly non-cardiac), cardiac arrest, emergency revascularization, cardiogenic shock, arrhythmia requiring intervention, AMI	30-day; MRR, phone follow-up	ASPECT ADP **Derivation study**	48 (1.3)	421 (11.8)
Than 2012	2 tertiary EDs Australia and New Zealand	1 975	1 185 (60.0)	60.4 (SD 14.9)	Universal	Death (unless clearly non-cardiac), cardiac arrest, emergency revascularization, cardiogenic shock, arrhythmia requiring intervention, AMI	30-day; phone follow-up; MRR, national health event search (identifies any death)	ADAPT ADP **Derivation study**	0	302 (15.3)
Than 2014	2 tertiary EDs Australia & New Zealand	Derivation 1 974 Validation 608	1184 (60.0)	60.5	AHA case definitions	AMI, emergency revascularization, death (cardiac causes), ventricular arrhythmia, cardiac arrest, cardiogenic shock or high atrio-ventricular block	30-day; phone follow-up, MMR, electronic health events search (which identifies any deaths)	EDACS ADP **Derivation study** **Internal validation study**	0 0	305 (15.4) 79 (13)

Note: ESC/ACC = European Society of Cardiology/American College of Cardiology; AHA = American Heart Association; AMI = acute myocardial infarction; MRR = medical record review
[†]For purpose of comparison, we used 30-day measures

Table 4 Authors and risk stratification tools

Tool	**No. of studies**	**Studies**
NHFA/CSANZ	2	Burkett 2014, Cullen 2013
Goldman	1	Burkett 2014
TIMI	8	Burkett 2014, Cullen 2013, Graham 2014, Graham 2014 (Front door TIMI), Backus 2013, Kelly 2013 Than 2011 (ASPECT ADP), Than 2012 (ADAPT ADP)
GRACE	2	Cullen 2013, Backus 2013,
NACPR (age<50 and age<60)	1	Hess 2012
Vancouver	3	Scheuermeyer 2014, Cullen 2014 (cTnI data), Cullen (hsTnI data)
HEART	1	Backus 2013
EDACS	1	Than 2014 (ADP)

all had published data ensuring transparency in combination with other studies. Several studies presented data in such a way that cohorts could simply be combined,this was possible for TIMI (Backus, et al., 2013; Burkett, Marwick, Thom, & Kelly, 2014; Cullen et al., 2012; Graham, Chan, Chan, Cattermole, & Rainer, 2014; Kelly, 2013), GRACE (Backus et al., 2013; Cullen et al., 2012) and the Vancouver chest pain rule (Cullen, Greenslade, Than et al., 2014; Scheuermeyer, Wong, Yu et al., 2014), all other tools were represented in the analysis by one study only. The combination of raw data was considered appropriate because the eligibility criteria for all studies was inclusive (all adult chest pain presentations to ED) rather than differentially selective (although Burkett 2014 study using the Goldman rule excluded patients under the age of 30). Additionally, the validation and derivation cohorts were combined for Than 2014 using EDACS ADP and Scheumeyer, 2014 using Vancouver Rule.

Table 5 only shows those tools and discharge criteria that yielded a sensitivity of >95%, that is a less than 5% MACE rate discharged patients. The exceptions to the 5% cut-off were: the Goldman assessment tool, which as implemented by Burkett 2014 gave 9% MACE in discharged patients, and the FD TIMI with a discharge

criterion of 0 and 1, which gave 8.6% MACE but was included as a comparator for the ordinary TIMI score with the same discharge criterion.

The risk stratification tools were compared by calculating the number and percentage of discharged patients who subsequently experienced an episode of MACE after discharge and the percentage of patients whose scores would have recommended admission that did not experience a MACE – See Table 5.

Discussion

Whilst other studies (Backus et al., 2011; D'Ascenzo et al., 2012; Yan et al., 2007) have compared the diagnostic accuracy of risk stratification tools in patients with confirmed acute coronary syndrome, this is the first review that has compared risk stratification tools for the cohort of patients with undifferentiated chest pain presenting to ED. Our goal was to compare the commonly used risk stratification tools used to predict the risk of MACE for patients presenting to rural EDs with chest pain. Using a comprehensive search strategy we were able to identify eight different risk stratification tools. This review did not identify any study that evaluated risk stratification tools in the rural ED population. Although the tools compared in this review have been validated in the ED setting none have been studied in the rural context which may limit generalisability of the findings.

When considering the tool which is best used in the rural setting where there are difficulties in access to functional testing and a reliance on point of care testing, the first factor to consider is the acceptable rate of MACE in patients who are discharged from the ED. Patients sent home with undiagnosed ACS have a 30-day mortality rate almost double that of those who are admitted to hospital (Pope, Aufderheide, Ruthazr et al., 2000). A recent survey (Than, Herbert, Flaws et al., 2013) of ED clinicians on what they considered an acceptable rate of MACE in discharged patients found that the modal value was 1% (264/1029 respondents), but 610/1029 (59%) stated a lower figure, ranging from 0.5% to zero. The second factor is the discharge rate of the tool concerned – criteria for the ideal tool will discharge the maximum possible proportion of patients and retain all of the MACE cases. If a 1% MACE rate is considered, as an acceptable rate for the discharged patients, then the tool with the highest discharge rate that achieves this is EDACS-ADP which discharges 44.5% of patients and also has one of the lowest rates of MACE in those discharged (3/1148, 0.3%). Only the GRACE tool had a higher discharge rate (69%

Table 5 Percentage MACE in Admitted and Discharged Groups

Tool	No.	Discharge Criterion	Number Discharged (%)	No. of MACE in Discharged group (%)	No. Admitted (%)	No. of MACE in Admitted group (%)
ASPECT ADP	3582	ASPECT ADP negative	352 (9.8)	3 (0.9)	3230 (90.2)	418 (12.9)
ADAPT ADP	1975	ADAPT ADP negative	392 (19.8)	1 (0.3)	1583 (80.2)	301 (19.0)
EDACS ADP	2582	EDACS ADP Low Risk	1148 (44.5)	3 (0.3)	1434 (55.5)	381 (26.6)
FD TIMI	925	0 only	150 (16.2)	2 (1.3)	775 (83.8)	117 (15.1)
FD TIMI	925	0 & 1	382 (41.3)	33 (8.6)	543 (58.7)	119 (21.9)
Goldman	279	Very low risk Low risk	134 (48.0)	12 (9.0)	145 (52.0)	29 (20.0)
GRACE	948	<50	229 (24.2)	1 (0.4)	719 (75.8)	90 (12.5)
GRACE	948	<100	653 (68.9)	28 (4.3)	295 (31.1)	90 (30.5)
GRACE	2388	<60	335 (14.0)	10 (3.0)	2053 (86.0)	430 (20.9)
HEART	2388	0-3	870 (36.4)	15 (1.7)	1518 (63.6)	392 (25.8)
NACPR<50	2718	Early Discharge	497 (18.3)	0 (0.0)	2221 (81.7)	336 (15.1)
NACPR<60	2718	Early Discharge	805 (29.6)	4 (0.5)	1913 (70.4)	332 (17.4)
Vancouver chest pain rule (HsTnI)	1635	Early Discharge	212 (13.0)	3 (1.4)	1423 (87.0)	331 (23.3)
Vancouver chest pain rule (cTnI) †	3296	Early Discharge	503 (15.3)	5 (1.0)	2793 (84.7)	613 (21.9)
NHFA/CSANZ	948	Low risk	12 (1.3)	0 (0.0)	936 (98.7)	91 (9.7)
NHFA/CSANZ	948	Low and Intermediate	632 (66.7)	20 (3.2)	316 (33.3)	72 (22.8)
TIMI‡	2152	0 only	396 (18.4)	4 (1.0)	1756 (81.6)	248 (14.1)
TIMI§	3592	0 & 1	1267 (35.3)	37 (2.9)	2325 (64.7)	528 (22.7)

† Scheuermeyer 2014, Cullen 2014 (cTnI) combined; ‡ Burkett 2014, Cullen 2013, Kelly 2013 and Graham 2014 data combined; § Burkett 2014, Graham 2014 ands Backus 2013 data combined (Cullen 2013 did not provide data that could be used for a discharge score of <2).

if all patients with scores <100 are discharged) but this was achieved at the expense of an unacceptably high MACE rate of 4.3% in discharged patients. On the other end of the scale, HFA/CSANZ guidelines achieved zero cases of MACE in discharges but discharged only 1.3% of patients, leading to a very high false discovery rate of 90.3%.

Economic impact may also be considered in evaluating tools used for risk stratification for patients presenting to EDs with chest pain. Whilst not initially a goal of this systematic review, an opportunity to compare the economic impact of the

various tools arose when a recently published prospective study (Cullen et al., 2015) found the mean cost per patient presenting to ED with chest pain was $5,272. In order to compare the economic burden that would be imposed by admission of ED patients with chest pain, the cost of admitting those not stratified as low risk by the various tools was calculated per 1,000 ED admissions which allowed for the calculation of cost per episode of MACE. See Table 6.

The ideal risk stratification tool would exclude patients who have no risk of ACS from testing and unnecessary intervention whilst rapidly identifying those for who early management and referral is indicated thereby saving resources and not having an adverse impact of health outcomes. In Australia, many clinical pathways for the management of patients presenting to hospital with undifferentiated chest pain rely on risk stratification utilising the NHFA/CSANZ risk stratification tool (The Cardiac Society of Australia and New Zealand Acute Coronary Syndrome Guidelines Working Group & National Heart Foundation of Australia, 2006). These guidelines are the most expensive in terms of admission cost per 1,000 ED presentations ($5,203,464) and per episode of MACE observed ($53,644). Although no MACE occurred in patients who were classified as low-risk by these guidelines, this was at the expense of an extraordinarily high rate of admission (nearly 99% of all ED presentations). A cost–saving could be achieved if both low- and intermediate- risk patients (67%) were considered suitable for discharge. Similarly, using a GRACE score cut-off of <100 allowed discharge of nearly 70% of presentations. However, by using these discharge criterions there were MACE rates of 4.3% and 3.2% respectively in discharged patients, which are unacceptably high rates. The cheapest tool giving a ≤1% MACE was the EDACS ADP, which had one of the lowest rates of MACE in the discharged group (0.3%) and the highest rate of MACE in the admitted group (26.6%). Accordingly, the mean cost of admission per 1,000 ED presentations was calculated to be $2,925,960 and $11,000 per episode of MACE. This higher proportion of patients who are able to be safely discharged and the lower economic burden indicate the EDACS-ADP is the most effective discriminatory tool for use in patients with chest pain presenting to EDs. In making this finding we did not take into account any differences in logistic burden or costs between the various risk stratification tools. We also assumed the populations

Table 6 Risk stratification tool and cost per episode of MACE

Tool	Discharge Criterion	% Admitted	Mean Admission Cost per 1,000 ED presentations	% MACE in Discharged group	% MACE in Admitted group	Cost per episode of MACE
NHFA/CSANZ	Low and Intermediate	33.3	$1,755,576	3.2	33.3	$5,272
GRACE	<100	31.1	$1,639,592	4.3	30.5	$5,376
EDACS ADP	EDACS ADP Low Risk	55.5	$2,925,960	0.3	26.6	$11,000
HEART	0 - 3	63.6	$3,352,992	1.7	25.8	$12,996
Goldman	Very low risk Low risk	52.0	$2,741,440	9.0	20.0	$13,707
FD TIMI	0 & 1	58.7	$3,094,664	8.6	21.9	$14,131
TIMI[†]	0 & 1	64.7	$3,410,984	2.9	22.7	$15,026
Vancouver chest pain rule (hsTnI)	Early Discharge	87.0	$4,586,640	1.4	23.3	$19,685
Vancouver chest pain rule (cTnI)[‡]	Early Discharge	84.7	$4,465,384	1.0	21.9	$20,390
NACPR<60	Early Discharge	70.4	$3,711,488	0.5	17.4	$21,330
GRACE	<60	86.0	$4,533,920	3.0	20.9	$21,693
ADAPT ADP	ADAPT ADP negative	80.2	$4,228,144	0.3	19.0	$22,253
NACPR<50	Early Discharge	81.7	$4,307,224	0.0	15.1	$28,525
FD TIMI	0 only	83.8	$4,417,936	1.3	15.1	$29,258
TIMI[§]	0 only	81.6	$4,301,952	1.0	14.1	$30,510
GRACE	<50	75.8	$3,996,176	0.4	12.5	$31,969
ASPECT ADP	ASPECT ADP negative	90.2	$4,755,344	0.9	12.9	$36,863
NHFA/CSANZ	Low risk only	98.7	$5,203,464	0.0	9.7	$53,644

[†] Burkett 2014, Graham 2014 ands Backus 2013 data combined; [‡] Scheuermeyer 2014, Cullen 2014 (cTnI) combined; [§] Burkett 2014, Cullen 2013, Kelly 2013 and Graham 2014 data combined

included in each study had similar characteristics for acknowledged risk factors for MACE. The review benefits from a comprehensive literature search that aimed to identify all published studies. Wide search terms and reputable electronic databases were implemented in the search strategy. The use of a validated tool in the quality assessment of studies and our summary was based on recommended methods and

was another strength of the review. To increase the applicability and reliability of the summary findings, we included only prospective studies that investigated patients presenting to ED with undifferentiated chest pain.

Our review has some limitations. We found between-study heterogeneity in the troponin assay that was utilised; although there were differences in the specific assays used, the use of troponin as the sole cardiac biomarker in determination of the risk score was common to all. Secondly we compared the findings from derivation, external and internal validation studies of risk stratification scores. Although the EDACS-ADP was found to be the best performing tool, this finding was made using the results of a single study that used a derivation and an internal validation cohort of undifferentiated ED chest pain patients. Additionally, patients at risk of ACS presenting with atypical chest pain were not included in the studies identified for this review which limits the application of these findings to those who have chest pain as the presenting symptom. There is also a small potential for missed studies using our search strategy, particularly by the limiting of included studies to English language only. Lastly, there are no studies published in the contemporary literature that have attempted to quantify the cost of chest pain presentations to rural EDs. The mean admission cost that was used for the economic discussion in this review is derived from a prospective study at a major metropolitan hospital. It is unclear how this cost relates to the rural context.

Conclusions

Implications for practice

Whilst most patients who present to ED with chest pain will not have an ACS, assessments are required to determine those who are suitable for discharge and those who require early management and referral. The ideal risk stratification tool used in this assessment should exclude patients who have no risk of ACS from testing and unnecessary intervention whilst rapidly identifying those needing further investigation and treatment. The current NHF/CSANZ guideline recommendations include a lengthy and resource intensive period of assessment for the majority of patients. The EDACS ADP appears most suitable for use in an undifferentiated chest pain population presenting to EDs. By using this risk stratification tool, there is demonstrated economic benefit without compromising patient safety or quality of care. Another benefit of using the EDACS-ADP is that it is simple to apply in the

real-world setting and does not rely on health technologies that are not available in rural and remote settings.

Implications for research

Application of the EDACS ADP has the potential to increase the efficiency of diagnostic investigation; patients who meet the criteria for early discharge from the ED could be safely discharged with a low incidence of MACE, and patients who do not could be considered for additional investigation, treatment and/or early referral. Further assessment of the EDACS ADP, particularly in the rural context, is recommended.

Although for emergency physicians the acceptable missed event rate for MACE in discharged patients has been reported to be ≤1%, it remains unknown what event rate is acceptable to rural clinicians and patients. Further research is recommended.

Acknowledgements

We would like to acknowledge Mr Peter Sondergeld, liaison librarian, Queensland University of Technology for assistance in the literature search. We would also like to thank the many study authors who provided additional information regarding their research.

Authors' contributions

TR and GG conceptualised the study. All authors participated in the study design. TR, NFH, NJ, SC, ML and JO'C participated in the acquisition, analysis and interpretation of data. EG advised on statistical considerations and participated in analysis and interpretation of data. TR drafted the manuscript with all authors contributing to its refinement. GG critically reviewed the manuscript. All authors read and approved the final manuscript.

Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

END OF MANUSCRIPT

References for the manuscript are included in the thesis reference list

2.4 SUMMARY AND IMPLICATIONS

The review identified and critiqued the literature reporting evaluation studies of the effectiveness of the ENP service. Using a comprehensive search strategy, 41 national and international studies that evaluated ENP service were appraised. The findings of three systematic reviews that have evaluated the safety and quality of ENP service has been provided. Following on from this, after review of the remaining studies, three themes were identified and a narrative analysis was presented.

The beneficial effect of an ENP service in meeting organisational goals or key performance indicators is evidenced in the influence of the service. Shorter length of stay and waiting times for patients managed by an ENP service and a lower proportion of patients who left without being seen were demonstrated, however these findings need further consideration. The use of ENP service may have increased the number of clinicians able to assess and treat patients and this beneficial effect may have occurred with the addition of any service provider. Further, these studies did not account for the differing responsibilities of clinicians, with the ENP service limited to a very specific cohort presenting with minor injury and illness. Despite these caveats, the ENP service has been identified as employing processes of care that result in time-related advantages for patients presenting to the ED.

High levels of patient satisfaction and the acceptability of the ENP service have been clearly established without reservation. The majority of patients find ENPs competent in providing care and are satisfied with their overall care. In evaluating the substance of this nursing care and its influence on outcomes, the 'attentiveness' and 'comprehensiveness' of the ENP service with a focus on patient education and counselling were identified as contributing to these higher levels of patient satisfaction.

The clinical effectiveness of the ENP service has been established through study of the quality of referral to other health professionals, therapeutic interventions and the ordering and interpretation of diagnostic investigations. ENPs have been shown to effectively use clinical tools that support the provision of evidence-based health care with a diagnostic accuracy that is at least equivalent to medical doctors.

While the evidence supports the use of an ENP service, it should be noted that these studies were mostly conducted in the context of minor injury and illness presentations and in metropolitan settings. Beyond this context, the safety and quality of the ENP service is not well researched and is poorly understood. Furthermore, the preponderance of studies used comparisons with medical practitioners and measures which may be insensitive to the contribution of nursing to patient outcomes. The other major limitation of the evidence is the lack of a standard definition and the variability in the clinical skills and knowledge for ENPs that precludes comparison between studies. In the same way, the inclusion of ENP candidates (who do not have the legislated authority and privileges of qualified ENPs) in studies of ENP service effectiveness impacts on research validity and generalisability. Future research on the evaluation of ENP service effectiveness should centre on authorised ENPs working in an established service. In order to gain further knowledge about the safety and quality of the service, research is required to examine the structural issues, the processes of care and the effectiveness of ENP service in the management of patients presenting with complex needs in rural settings.

The Donabedian SPO framework was presented a basis for further rigorous, multidimensional evaluation of the ENP service innovation. Examination of the structure of care for patients with chest pain who are managed by the ENP service was required to identify the limitations and advantages of this model of care. Evaluating the process and outcomes of care for the ENP service for this cohort of patients assisted in determining the quality of care provided. Further, by using a Donabedian approach, the strengths and weaknesses of each of these components and the implications for the safety and quality of the service was identified.

Chapter 3: Preliminary Study

3.1 INTRODUCTION

The preliminary audit study was a retrospective review of patients presenting with chest pain over a three-month period to two rural EDs in Queensland, Australia. The aim of this study was twofold: (i) to obtain knowledge about this patient population and the process of care; and (ii) to contribute to sample size estimation and anticipated time frame for recruitment for the proposed research.

All adult patients aged over 18-years presenting with chest pain to two rural EDs in Queensland, Australia from 1st September 2013 to 30th November 2013 were included in the review. Data were collected from the Emergency Department Information System (EDIS™), a computerised management program currently used in both research sites. Data collected for each patient included demographic information such as age and gender, service information including time to treatment, arrival and discharge times, waiting times, clinical information on discharge diagnosis and unplanned re-presentations. The Townsville Hospital and Health Service Human Research Ethics Committee on 19th November 2013 granted ethics approval (HREC reference number: HREC/13/QTHS/158) (Appendix B). The study was granted ethics exemption by the QUT Research Ethics Unit (Appendix C). Permission to use the de-identified data was granted from the Queensland Health Data Custodian (Appendix D).

The following pages present the manuscript that reports the findings of the audit study that was published by the "Australian Journal of Rural Health".

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2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
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Retrospective observational study of patients who present to Australian rural emergency departments with undifferentiated chest pain.

Australian Journal of Rural Health (2014) 22, 229-234.

Contributor	Statement of contribution*
Tina Roche 15/09/16	Study design, data analysis, interpretation of results, manuscript preparation, final approval of manuscript
Glenn Gardner	Study design, data analysis, interpretation of results, manuscript revision, final approval of manuscript
Peter Lewis	Study design, interpretation of results, manuscript revision, final approval of manuscript

Principal Supervisor Confirmation

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Glenn Gardner
Name

Signature

15/09/16
Date

3.1.1 Publication – Preliminary study

AJRH The Australian Journal of Rural Health

Aust. J. Rural Health (2014) **22**, 229–234

Original Research

Retrospective observational study of patients who present to Australian rural emergency departments with undifferentiated chest pain

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Retrospective observational study of patients who present to Australian rural emergency departments with undifferentiated chest pain.

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DOI: 10.1111/ajr.12134.

Australian Journal of Rural Health (2014) 22, 229-234.

Journal Metrics	
Impact factor	1.225
H index	33
SCImago Journal Rank (SJR)	0.51 Q2

Abstract

Aim**:** To identify the demographic and clinical characteristics of patients who present to Australian rural emergency departments with chest pain.

Design: Retrospective, observational study

Setting: Rural emergency departments (ED) in Queensland, Australia

Participants**:** 337 consecutive adult patients with undifferentiated chest pain that presented between 1st September 2013 and 30th November 2013.

Main outcome measures**:** Service indicators, discharge diagnoses and disposition

Results**:** Presentations for undifferentiated chest pain represented 3.5% of all patient presentations during the sampling period. The mean age of patients was 48 years and 54% were male. Overall, 92% of patients left the ED within the 4-hour NEAT target. The majority of presentations were related to cardiac concerns (39%), followed by non-cardiac chest pain (17%), musculoskeletal (15%) and respiratory (10%) conditions. More than half of these patients were discharged at the completion of the ED service (52.8%), 40.6% were admitted, 3.3% left at own risk, 2.4% did not wait and less than 1% of patients required transfer to another hospital directly from the ED.

Conclusions**:** This study has provided information on the characteristics and processes of care for patients presenting to Australian rural EDs with undifferentiated chest pain that will inform service planning and further research to evaluate the effectiveness of care for these patients.

Keywords**:** rural health services, emergency treatment, demographics, quality of care, clinical characteristics

What is already known on this subject:

- *Chest pain is a common presentation to EDs and may be caused by benign or life threatening conditions*
- *Little is known about the demographic and clinical characteristics for patients with chest pain presenting to Australian rural EDs*

What this study adds:

- *Information from systematic research on the characteristics of patients presenting to Australian rural EDs with chest pain*
- *New knowledge on ED service indicators of wait time and "did not wait" for patients presenting with chest pain*

Introduction

Chest pain is a common presentation to emergency departments (ED) consistently ranking in the top five Disease Related Groups (Groarke et al., 2013). Across the United States and Europe, chest pain represents approximately 15 million presentations per year to ED (Groarke et al., 2013) and has both benign and life-threatening aetiologies. The challenge for health services is to provide a high degree of safety in chest pain assessment and management in a timely and cost-effective manner in an era of increasing demand (Parsonage et al., 2013). Systems are needed to ensure the rapid identification and treatment of serious disease related to chest pain whilst maximising the number of patients able to be safely discharged home with diagnosis and treatment of stable conditions (Morris & Whiteside, 2009). The epidemiology and processes of care for patients presenting to metropolitan EDs with undifferentiated chest pain is well reported, however, little is known about their rural counterparts.

In rural areas, people are less likely to survive or receive recommended care when experiencing an acute coronary syndrome (ACS) (Kinsman, Tori, Endacott, & Sharp, 2007) due to a lack of qualified staff to provide care, inconsistent use of protocols and limited availability of rapid transfer to tertiary care (Ellerbeck, Bhimaraj, & Perpich, 2004). Unnecessary transfer to tertiary hospitals is disruptive and stressful to patients and their families as well as costly to the health care system (Westfall et al., 2006). To ensure successful outcomes for patients with undifferentiated chest pain, clinicians in rural EDs need to be skilled in diagnosis and

accurately discriminate those presentations able to be managed locally using available resources and those who require transfer to tertiary centres for further treatment.

This study had two aims: firstly, to examine the demographic and clinical characteristics of patients presenting to Australian rural emergency departments with undifferentiated chest pain; and second to evaluate ED service indicators for this patient cohort.

Methods

Study design

This was a retrospective, observational cohort study conducted from 1st September 2013 to 30th November 2013.

Sample and Setting

The study setting was two rural hospital EDs in Queensland, Australia – both EDs offer 24-hour, 7-day a week adult and paediatric emergency health care and are capable of providing initial treatment and care, resuscitation and stabilization and transfer to a higher-level services as necessary (Queensland Health, n.d.-a). The EDs are staffed by medical, nursing and emergency nurse practitioner (ENP) clinicians. The ENP service at these facilities is well established with a diverse practice scope that extends beyond the treatment of minor injury and illness to encompass the care of patients presenting with complex problems including undifferentiated chest pain (Queensland Health, n.d.-b).

The study sample was all eligible patients presenting to these EDs in the sampling time frame - 1st September 2013 and 30th November 2013.

Inclusion criteria

All consecutive adult patients (age 18-years or older) with "pain (not associated with acute injury) – chest" recorded as the presenting complaint at triage. Children and adults presenting with chest pain as the result of an acute injury (traumatic) were excluded from the study.

Data collection

Data were collected from the Emergency Department Information System (EDIS™), a computerised management program currently used in both research

sites. Data collected for each patient included demographic information such as age and gender, service information including time to treatment, arrival and discharge times, waiting times, and clinical information on discharge diagnosis and unplanned re-presentations.

Ethical considerations

The relevant institutional Human Research Ethics Committees approved the study in December 2013.

Data analysis

The ED service indicators examined included waiting time, length-of-stay (LOS) and unplanned representation rates for patients with undifferentiated chest pain. The Australasian Triage Scale is an indicator of clinical urgency where a number corresponds to the recommended timeframe in which a patient should receive treatment (Australasian College of Emergency Medicine, 2002). The triage nurse following initial assessment assigns the ATS on a patient's arrival. Waiting time was defined as time in minutes from initial triage until the treating clinician for that patient was registered in EDIS. LOS was defined as the time in minutes from initial registration until the time of the patients "actual" departure from the ED as recorded in EDIS. Unplanned representation within seven-days was examined by analysing data that were provided by the triage nurse on registration, where visit type was recorded as "unplanned representation" for the current complaint. The discharge diagnosis was defined as that recorded in EDIS by the attending clinician at the patient's time of departure from the ED. No follow up of patients was undertaken.

All data were de-identified. Demographic characteristics (age, gender), ED characteristics (ATS, discharge diagnoses, discharge destination) and outcomes (waiting times, LOS, unplanned representations) were analysed using descriptive statistics (e.g. mean, median and interquartile range for continuous variables, frequencies and percentages for categorical variables). Missing data were found in 14 presentations (4%) and was specific to the variable of treating clinician – remaining data from these presentations were included in the analysis.

Results

A combined sample of 9,860 patients presented to the EDs of Hospital 1 (n=1,942) and Hospital 2 (n= 7,918) EDs between 1st September 2013 and 30th

November 2013 and of these, 3.5% (n=348) patients met study inclusion criteria. Of these 348 patient presentations, 11 patients were paediatric presentations (age less than or equal to 17-years at presentation) and therefore not eligible. A sample of 337 consecutive adult patients presenting with undifferentiated chest pain were included in the study.

Demographic characteristics

The majority of patients presenting with undifferentiated chest pain self-presented to the ED; were male with a mean age of 48 years. The patient characteristics for the study population are presented in Table 6.

Service indicators

Median waiting time to be seen for patients with undifferentiated chest pain was 4 minutes (IQR 8) and the median length of stay for patients with a discharge disposition of "home" was 100.5 minutes (IQR 90, p=0.02), for admission was 101 minutes (IQR 88.5, p=0.02) and 100 minutes (IQR 89, p=0.02) for patients who transferred to other health care facilities. Overall, 92% of patients (n=310) left the ED within the 4-hour service target. During the study period, only two (0.6%) unplanned representations within seven days were recorded.

Table 7 Patient characteristics

	Min	Max	Mean
Age, yrs.	18	92	48
Male gender, %			54
Mode of Arrival		N	%
Walked in (Public or private transport)		246	73
Ambulance – RFDS flight		11	3.3
Ambulance – Paramedic/Patient transport officer		79	23.4
Police or prison vehicle		1	0.3
TOTAL		337	100

Discharge diagnoses

Cardiac conditions were implicated in the majority of presentations (39% of all presentations for undifferentiated chest pain), followed by non-cardiac chest pain (17%), musculoskeletal (15%) and respiratory (10%) conditions. The remainder of

presentations included diagnoses for psychiatric, infectious, gastrointestinal, neurological and other conditions (Figure 7). The single most common discharge diagnosis was "possible cardiac chest pain" which represented 23.1% of all presentations (n=78). A list of the 12 most common discharge diagnoses is provided in Table 7. In total, there were 73 different discharge diagnoses given for patients with undifferentiated chest pain.

Discharge disposition

More than half of the patients presenting with undifferentiated chest pain were discharged at the completion of the ED occasion of service (52.8%, n = 178), 40.6% were admitted to the health service, 3.3% left at own risk after service was commenced, 2.4% did not wait for treatment and less than 1% of patients required transfer to another hospital directly from the ED. See Figure 8.

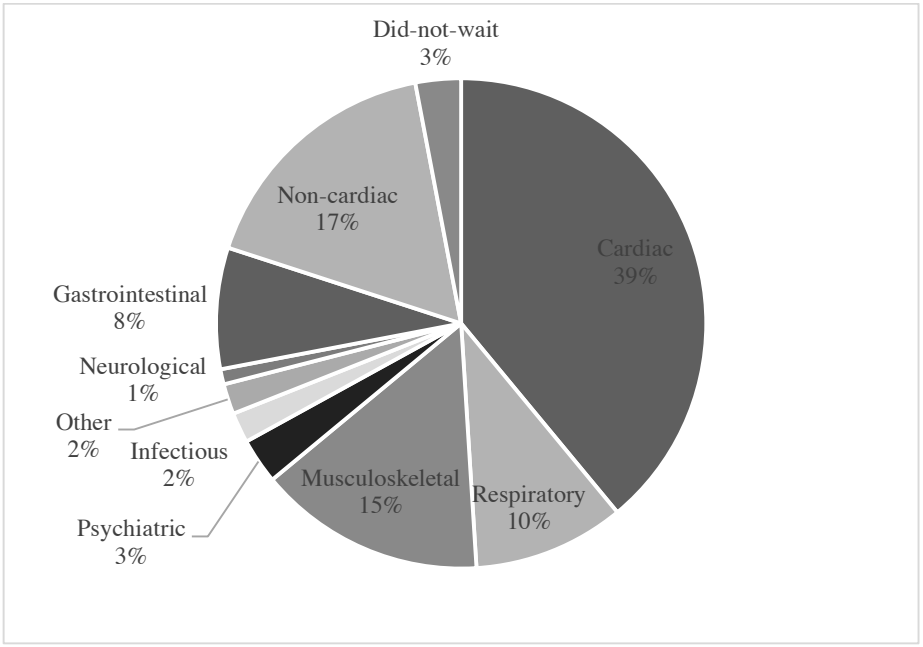

Figure 5 Diagnosis on discharge by cause

Table 8 The 12 most common discharge diagnoses

Ranking	N =	%	ICD Descriptors
1	78	23.1	Possible cardiac chest pain
2	55	16.3	Non-cardiac chest pain
3	12	3.6	Angina pectoris - stable
4	11	3.3	Rib sprain/strain
5	10	3.0	Costochondritis
6	9	2.8	Gastro-oesophageal reflux
7	8	2.4	Acute coronary syndrome
8	7	2.1	Myocardial infarction - acute
9	7	2.1	Pneumonia - unspecified
10	6	1.8	Anxiety
11	6	1.8	Atrial Fibrillation
12	6	1.8	Gastritis
TOTAL	215	63.8	

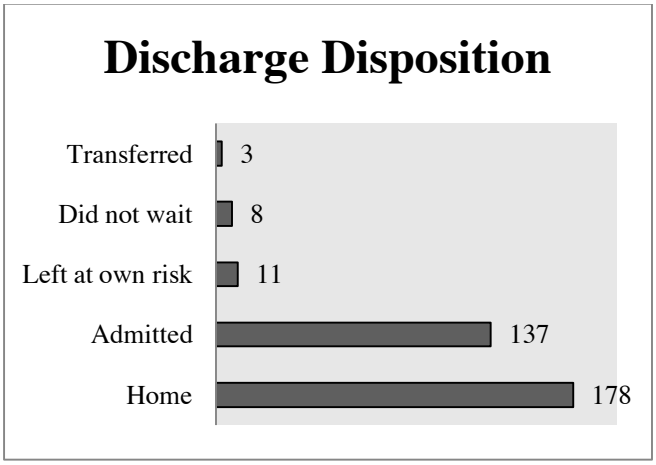

Figure 6 Discharge disposition

Discussion

Patients presenting with undifferentiated chest pain represented 3.5% of all presentations to these EDs in the study period. The observed prevalence of chest pain presentations in this study is greater than the results of retrospective audit of patients with chest pain presenting to metropolitan EDs in the UK (2.4%) (Fothergill, Hunt, & Touquet, 1993) and the United States of America (2.5%) (Kohn, Kwan, Gupta, & Tabas, 2005). Another prospective study (Goodacre et al., 2005) demonstrated a higher prevalence (6% of all presentations) at an English metropolitan emergency department, however, a possible explanation for this is that

more inclusive selection criteria were used than our study that included only patients presenting with a chief complaint of "chest pain".

Service Indicators

The EDs examined in this study demonstrated sound organisational and clinical effectiveness when managing patients presenting with undifferentiated chest pain. The median waiting time to be seen in this study was 4 minutes (IQR 8), which exceeds the benchmark for patients in emergent and urgent ATS Categories. This short waiting time may have contributed to the low rate of patients who did not wait for treatment (2.2%) when compared to another recent Australian study (10.2%) (Crilly, Bost, Gleeson, & Timms, 2012) and the Australian national average of 5.5% (Australian Hospital Statistics 2008-2009, n.d.). The National Emergency Access Target, or NEAT, is a performance benchmark for Australian public hospitals set under the National Partnership Agreement on Improving Public Hospital Services. Queensland public hospitals aim to have 77% of patients who present to an ED admitted, discharged or transferred within four hours of their presentation. In this study, the median length of stay for all groups of patients presenting with undifferentiated chest pain (discharge, admission or transfer) was around 100 minutes, with 92% of patients meeting the 4-hour service target, surpassing the NEAT targets set across the country. There were only two unplanned representations within seven days to the ED during the study period. Neither of these patients experienced a life-threatening event and both were subsequently discharged home from the ED the same day.

Discharge diagnoses

Proportions of patients presenting with chest pain from diseases of respiratory, gastrointestinal, cardiovascular and psychogenic systems correspond with other studies (Cilia et al., 2010; Kohn et al., 2005; Verdon et al., 2008); however, there were significant differences in the percentages of patients who were diagnosed with musculoskeletal chest pain. A relatively low proportion of patients (15%) were given a final diagnosis of musculoskeletal chest pain when compared to other studies (49%) (Cilia et al., 2010; Verdon et al., 2008). One possible explanation is that our study included patients for whom the diagnosis was not clear on discharge from the ED. Of the 40% of patients who were discharged from the ED with a diagnosis of

"possible cardiac chest pain" or "non-cardiac chest pain", it may be that a large number of these patients were experiencing chest pain from a musculoskeletal cause.

Discharge disposition

Our study showed that the proportion of patients presenting to the ED with undifferentiated chest pain that were subsequently admitted to hospital or discharged home was similar to rates found in other studies (Goodacre et al., 2005; Kohn et al., 2005). Of all admissions for patients with undifferentiated chest pain, a high proportion (49.6%) consisted of patients who were discharged from the ED with a diagnosis of "possible cardiac chest pain". This finding is consistent with contemporaneous clinical risk stratification strategies for the assessment of patients with chest pain, which focuses on the identification of ACS (after other obvious diagnoses have been excluded) using a strategic approach of a period of observation and repeated cardiac investigations (Parsonage et al., 2013).

Limitations

This study used a database of patient presentations to rural emergency departments to describe the demographic and clinical characteristics of patients presenting with undifferentiated chest pain. By using a retrospective study design, it is possible that some of the data was incomplete or inaccurate. By using two different non-interventional rural hospitals with a range of population groups and clinicians, the generalisability of these findings, although resonating with other rural services, is limited to service contexts with similar characteristics. To our knowledge, this is the only Australian study that has investigated the demographic and clinical characteristics of patients presenting to rural emergency departments with undifferentiated chest pain, which precludes comparison with other studies. Finally, the discharge diagnosis is based on assessment of the treating clinician and may have included patients for who the diagnosis was not clear on discharge from the ED. The use of independent observers and follow up of patients may have validated the diagnosis and strengthened the findings of this study; these resources were not available for this study. Notwithstanding these limitations this pragmatic research has provided information that will be useful for future studies.

Conclusion

This study has provided valuable information regarding the demographic and clinical characteristics of patients presenting to rural emergency departments with undifferentiated chest pain. Additionally, this study provided an evaluation of the ED service indicators, waiting time, LOS and unplanned representations for patients within this cohort in a rural emergency context. This data is useful to guide future studies that evaluate the processes of care for these patients.

Acknowledgements

The authors would like to acknowledge the cooperation of the participating health services for allowing the use of the data for this study.

Author contributions

TR conceived and designed the study with GG and PL. TR analysed the data under the guidance of GG. TR, GG and PL contributed to the interpretation of results. TR wrote the manuscript, and GG and PL revised it critically for important intellectual content. All authors approved the final manuscript.

Competing interests

None declared.

END OF PUBLISHED MANUSCRIPT

References for the submitted manuscript are included in the thesis reference list

3.2 SUMMARY AND IMPLICATIONS

Although the processes and outcomes of care for this patients presenting to EDs with chest pain have been well described previously, this knowledge was limited to the metropolitan context. Consequently, the preliminary study served to provide knowledge on patients presenting to rural hospitals with undifferentiated chest pain. Through the conduct of the study, insight into this patient cohort and the process of care was gained.

Chapter 4: Research Methods

4.1 INTRODUCTION

The results from the preliminary study reported in Chapter 3 showed that almost 40% of patients presenting to rural EDs with undifferentiated chest pain were assessed as having possible cardiac chest pain. This finding in combination with the current trends and issues related to the rural health workforce indicated the need for a large-scale study into the quality and safety of ENP service in the care of this cohort of rural patients.

This study was designed to meet this need and had two aims:

1. To examine the safety and quality of the ENP service model in provision of care in the rural ED environment; and
2. To evaluate the effectiveness of the ENP service model in the management of patients presenting to EDs with undifferentiated chest pain.

This Chapter presents detailed information on the features of this research including the methods and justification for the research approach. Following this, the Chapter introduces the guiding framework for this research and provides a rationale for the use of the Donabedian Structure-Process-Outcome framework. A manuscript reporting the study protocol that was published in the *British Medical Journal* is presented. Due the word limitations of publishing requirements, some important considerations for the research methods require further elaboration and/or clarification. Henceforth, this Chapter provides further detail about the models of care and examines the issues of data management and ethical considerations for the research including the potential problems and their management.

4.2 METHODOLOGY AND RESEARCH DESIGN

4.2.1 Methodology

The research used a prospective longitudinal nested cohort study to evaluate the safety and quality of ENP service in the management of patients presenting to rural EDs with undifferentiated chest pain. The literature review reported in Chapter

2 showed a paucity of research reporting evaluation studies of ENP service other than in the context of minor injury and illness. Additionally, most of this reported research had been conducted in metropolitan settings. Despite the increasing use of ENPs in rural EDs there was a scarcity of research reports in the national and international literature regarding the use of these clinicians in this service context.

Although randomised controlled trials (RCTs) are considered the "gold standard" for research in the area of healthcare, use of this approach is not realistic in all research contexts (Hood, 2009; Silverman, 2009). In terms of this reported research, the aim was to evaluate an established rural ENP service in the management of patients presenting with chest pain. The size and geographical dispersion of ED services in the participating rural hospitals, determined that it was not feasible to implement a service intervention with fidelity and adequately identify and control for variables. In some of these EDs at times the ENP was the only clinician and randomisation of patients across centres was not feasible on logistical, clinical and ethical grounds; access to treatment for this cohort of patients could not be delayed. Furthermore, an RCT does not have the flexibility to evaluate the complex combinations of service interventions and practices in terms of their real world effectiveness (Horn & Gassaway, 2007; Soh & Saw, 2010) required by the multidimensional Donabedian framework. A well-designed cohort study is a powerful study design for describing and analysing the association between variables and multiple outcomes simultaneously (Hood, 2009; Silverman, 2009) and can produce results similar to RCTs (Concato, Shah, & Horwitz, 2000). Through use of a cohort design it is possible to ascertain the temporal relationship between the exposure and its association with outcomes (Hood, 2009; Soh & Saw, 2010; Song & Chung, 2010). Using this knowledge, a cohort design was chosen for this research that aimed to investigate the effectiveness of the rural ENP service model and its association with multiple outcomes that include clinical effectiveness, organisational effectiveness and patient-reported outcomes.

In research situations where the experimental design is not feasible the prospective cohort design is the strongest approach in its capacity to include strategies to minimise bias and other threats to validity (Black, 1996; Concato et al., 2000). The prospective nature of the research minimises the likelihood of recall bias because patients are observed forward in time (Silverman, 2009); the researcher has

control over data collection ensuring complete, accurate and consistent measurement between participants. Selection bias and confounding may compromise the internal validity of observational studies. This may occur when an observed outcome can be related to underlying differences in patient characteristics leading to problems in establishing a clear cause-and-effect relationship. In reducing selection bias, one of the strengths of this study is that a critical characteristic of participant selection is that both the ENP and standard care groups are selected from the same source population. Additionally, extensive patient data were collected in order for patient demographics and baseline differences between the ENP and standard care group to be assessed to identify a possible selection bias. Finally, the last major disadvantage of this study design is the potential for loss to follow-up. In this study the interval between exposure and outcome measurements are short to minimise loss to follow-up.

In addition, by using this design for the research a further cohort study was able to be conducted that was nested within the original prospective cohort. From the cohort of patients presenting with chest pain, patients with suspected or confirmed acute coronary syndrome were able to be identified. This nested cohort was identified as being ideal for the comparison of ENP service to standard care in the utilisation of evidence based guidelines and diagnostic accuracy of ECG interpretation that may provide evidence of the safety and quality of the service model. The nested cohort design was able to utilise data that were collected for the full study cohort, thus avoiding the time and cost of beginning a new study allowing for statistically efficient analysis of data with substantial time savings (Hood, 2009). The strengths of using a prospective cohort study that were previously discussed were similarly conferred to this nested cohort.

With this knowledge in mind, there was a requirement to further develop the methodology for this evaluation of the ENP model of care as a rural health service innovation through the use of a theoretical framework. Using a theoretical framework can successfully guide evaluation of complexity, by facilitating the definition of the concepts relevant to the phenomenon of interest and outlining the relationships between concepts (Fawcett & Desanto-Madeya, 2013). Additionally, the use of a framework assists in refining operational definitions, identification of indicators for these concepts and the development of research questions to be

evaluated in the research (Fawcett & Desanto-Madeya, 2013). The Donabedian Structure-Process-Outcome framework (Donabedian, 1966) is ideally suited to these principles (Gardner, Gardner, & O'Connell, 2014) by accommodating the complexity of the multiple dimensions of the ENP model of care as a service improvement initiative.

4.3 THEORETICAL FRAMEWORK: THE DONABEDIAN MODEL

Avedis Donabedian first described his framework for examining health services and evaluating the quality of healthcare in 1966. The value of this framework is that it provides a model that supports systematic evaluation of health care services at the level of the patient-provider interaction (Donabedian, 1966). According to Donabedian, there are three dimensions from which conclusions about the quality of care can be drawn; these are structure, process and outcome (Donabedian, 1966). *Structure* refers to the attributes of the health care setting (material, human and organisational resources), *Process* refers to what is actually done in the giving and receiving of health care and *Outcome* refers to the effects of health care on patients and populations (Donabedian, 1988) (See Figure 7). In essence the model asserts that quality in health care is possible because there is a relational effect; good structures increases the likelihood of good processes, which increases the likelihood of good outcomes.

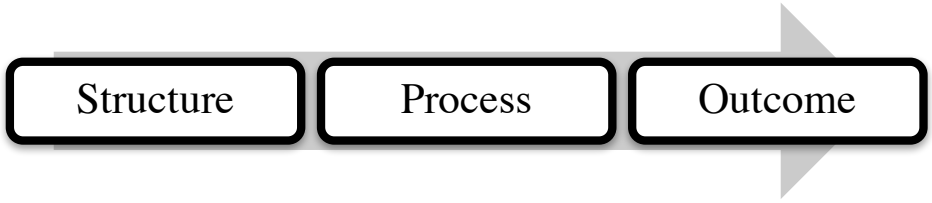

Figure 7 Donabedian's 1966 Structure-Process-Outcome Framework

The dimension of Structure of care includes physical, material and human resources and organisational factors, all of which influence the quality of health care (Donabedian, 1988). Although information about structure is easily ascertained to make inferences about quality, there needs to be a link between structure and process or structure and outcome that is often not well established (Donabedian, 1966). Although good structure is necessary for the delivery of quality health care, it does not guarantee quality processes or outcomes. Assessments of the Process of care assumes that quality involves consideration of whether good care (as is currently known) has been provided, rather than isolating evaluation of the outcomes of care that is given. Although process measures may be more relevant when evaluating practice, these assertions of quality are less stable and less final than those derived from the measurements of outcomes (Donabedian, 1966). The Outcome of care, in terms of clinical outcomes like surgical infection rate and mortality and morbidity measures, are accepted and frequently used indicators of quality in health care.

Although, these clinical outcomes are readily quantifiable, Donabedian asserted that measurement of outcomes can be difficult, sometimes irrelevant and can be influenced by many factors additional to medical *(sic)* care (Donabedian, 1966). Further, although assessment of quality through outcome measurement might indicate good or bad care on the whole, it cannot determine the strengths or weaknesses that lead to the particular outcome (Donabedian, 1966). The dimensions of structure, process and outcome are not attributes of quality but rather classifications for the types of information that can be obtained in order to infer that the quality of care is poor, fair or good.

The linear reasoning in Donabedian's early work has been critiqued (Mitchell, Ferketich, Jennings, & American Academy of Nursing Expert Panel on Quality Health Care, 1998) as a limitation of the model. Later work by Donabedian (Donabedian, 1988) addresses this in that he describes Structure, Process and Outcome as a triad with more complex associations forming a paradigm, where each of these dimensions is contingent on the previous, making the dimensions interdependent (Donabedian, 1988). Furthermore, in order to make inferences about quality, there needs to be an established relationship between the three dimensions before carrying out an assessment (Donabedian, 1988). The validity of any judgment of quality is dependent on the validity of the assumed causal linkage between the dimensions (Donabedian, 1988). This is more complex than the more simplistic association indicated in the original framework (See Figure 8).

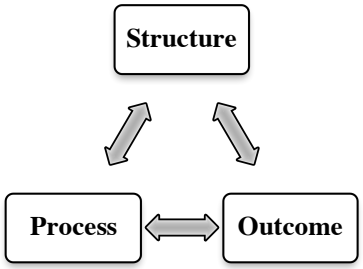

Figure 8 Donabedian's 1988 Structure-Process-Outcome Framework

4.3.1 Strengths and limitations of the framework

The Donabedian Structure-Process-Outcome (SPO) framework is one of the best known and widely used conceptual models (Lawson & Yazdany, 2012). Not-withstanding this familiarity, the simplistic structure of the model allows ready understanding of the concepts and effectively demonstrates the links between the

dimensions for those who are unaware of the framework. The comprehensiveness of the model facilitates an objective and systematic assessment of the safety and quality of ENP service and provides direction for future research.

The model allows for the identification of the variables that may be included in examination of the service model. Possible independent variables that can be included are (i) structural elements including patient and clinician characteristics; (ii) process elements such as the procedures involved in the provision of care, and; (iii) outcome elements including organisational and patient criteria.

On the other hand, there are limitations to the use of Donabedian's framework for this study. While Donabedian's model can identify relationships and associations between structure, process and outcomes, establishing these links is sometimes challenging and occasionally not helpful in determining causality. Understanding how structure and process affect outcomes for patients with chest pain has important implications that may affect policy, education and future research.

4.3.2 Previous applications of the framework

As noted in the previous section, there is a widespread familiarity with the Structure-Process-Outcome Framework and the flexibility of its application are reflected in the large body of literature that reports innovative and novel uses of the framework in the assessment of the quality of health care. For example, Donabedian's dimensions of Structure, Process and Outcome have been used to evaluate: the quality of discharge planning for elderly patients (Closs & Tierney, 1993); rehabilitation services for patients with spinal cord injury (Qu, Shewchuk, Chen, & Richards, 2010); assessing patient perception of the quality of nursing care (Kobayashi, Takemura, & Kanda, 2011) and to monitor and improve the quality of care for bariatric surgery services (Naranjo & Viswanatha, 2011).

Two specific studies in the field of evaluation of nurse practitioner service influenced the selection of the Donabedian framework to guide this research project. Sidani and Irvine (1999) adapted Donabedian's SPO framework to examine the contributions of the acute care nurse practitioner in delivery of quality health care (Sidani & Irvine, 1999). These researchers asserted that a model based upon the elements of Structure, Process and Outcome was necessary to address the complex system of factors inherent to the role which impact on the role's effectiveness.

Similar, Gardner et al. (2014) used the Donabedian SPO framework to examine the nascent nurse practitioner service in Queensland, Australia (Gardner et al., 2014). The selection of the SPO framework for this study, allowed for evaluation of the setting (structure) that care was delivered in, the clinical service provided (process) and the influence of the nurse practitioner service on patients (outcome). The study used a combination of audit, surveys, interviews, chart review and peer case review, and the findings supported the quality and safety of the service in terms of patient outcomes. Further, using this framework, these authors were able to identify improvements that could be made to structure and process elements required to optimise clinical outcomes.

4.3.3 Application of Donabedian's framework to this study

In light of the review of the strengths and limitations and previous applications of the Donabedian framework it was established that the framework was suitable for this evaluation of ENP service. According to the framework, in order to contribute new knowledge to this reform model our study needed to address the following research questions:

- What are the health service structures that influence the ENP delivery of safe, quality care for patients presenting to rural EDs with chest pain?
- Are the processes of care for patients who present to rural EDs with chest pain equivalent for patients managed by an ENP service to those managed in the standard model of care?
- Are the comparative outcomes for patients who present to rural EDs with chest pain equivalent for patients managed by an ENP service to those managed in the standard model of care?

This application of the Donabedian's framework, was further developed through alignment with the study hypotheses (see Chapter 1). These hypotheses include the evaluation of the ENP service model in the rural context with regard to multiple study outcomes. The indicators for each domain of the framework are presented below.

Structure Dimension

For this evaluation of the rural ENP service model, there was a requirement that health services demonstrate a structure that adequately supported the ENP in caring for the patient presenting with chest pain. Structure in this instance refers to the barriers and facilitators for ENP practice in the management of patients presenting with chest pain. Additionally, measureable data regarding the ENP characteristics of experience and perceived self-confidence was evaluated.

Process Dimension

In the management of patients presenting to rural hospitals with chest pain, demonstrating effective processes was imperative. In this instance, processes referred to the adherence to guidelines and diagnostic accuracy. Clinical practice, based on the best available evidence, ensures quality care of the chest pain patient. There are accepted recommendations and guidelines for the management of patients presenting to EDs with chest pain, for example, guidelines for the management of suspected or confirmed acute coronary syndromes (Chew et al., 2011). Such clinical guidelines provide the foundation for evidence-based practice on which safe and high-quality care is guaranteed. Although these guidelines are not specific to rural health services, there is a need to have practice based on these recommendations and other literature that support best practice for patients presenting with chest pain. Another important aspect for the care of patients presenting to rural health services with chest pain includes the identification of patients at high risk of ACS requiring early intervention and those at low risk of ACS who can be safely discharged from the ED. The risk stratification for patients with chest pain should be based on available guidelines and up-to-date research. Evidence based guidelines ensure safe and effective care delivery by the multi-disciplinary team.

Outcome Dimension

Evaluation of Outcomes allows for examination of the quality and safety of the service and can assist health services to identify potential areas for improvement. Comparing outcomes for rural patients with chest pain with their metropolitan counterparts was required to ensure the quality of care. Outcome measurements also offer data to health care providers, allowing development and implementation of evidence-based projects to enhance the care or services provided to this patient cohort.

Reporting the results and outcomes for patients presenting to rural EDs with chest pain is an important part of the quality evaluation. For this evaluation, the outcomes reviewed were service indicators including waiting time and length-of-stay and patient reported outcomes including satisfaction with care, quality-of-life and functional status.

4.3.4 Summary and implications

In the case of patients presenting to rural health EDs with chest pain there was a requirement to evaluate specific structure, processes and outcomes related to the quality and safety of the care provided. Utilising the Donabedian SPO framework strengthened this evaluation and provided opportunity for multi-faceted, rigorous health service research. This framework allows health care services to assess the totality of care delivered, as well as providing insight into how to evaluate the individual domains of care, such as structures and processes. The model then provides the health care team with framework to improve outcomes for patients with chest pain effectively.

Although there is no one recognised theoretical framework for use in health services research, the domains of quality assessment within Donabedian's SPO framework were ideally suited to the evaluation of the ENP service model in the management of a complex patient presentation, especially in light of the model being a rural health services innovation. This framework is identifiable and has easily understood concepts that were readily applied to this evaluation of the quality and safety of the ENP service model in the management of patients presenting to rural hospitals with chest pain.

4.4 STUDY PROTOCOL

Consistent with best practice in research the study protocol was published in a multidisciplinary research journal. Publication of the study protocol was also important in recognition of this study being the first to evaluate the effectiveness of ENP service in the management of a complex cohort of patients outside the metropolitan setting. Publishing the study protocol allowed for critical external review of the study design, informed others of the planned research supporting the potential for future research collaboration and allowed for scrutiny of comparisons between the planned protocol and what was actually conducted. The publication of a

study protocol is considered vital for observational studies (Godlee, 2001) to ensure fidelity with the study protocol where there is potential for findings to be influenced by results found during data analysis rather than those hypothesised at the beginning of the study. The protocol reported on the study design, with specific attention to the variables of interest and the outcomes to be considered. Data collection processes and the analysis plan was reported. An *a-priori* sample size calculation was explicitly described. The following sections present the published manuscript.

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The following is the format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified* that:

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2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
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Effectiveness of an emergency nurse practitioner service for adults presenting to rural hospitals with chest pain: protocol for a multicentre, longitudinal nested cohort study.

Article first published online: 12 February 2015.

Contributor	Statement of contribution*
Tina Roche 15/09/16	Study design, manuscript preparation, final approval of manuscript
Glenn Gardner	Study design, manuscript revision, final approval of manuscript
Peter Lewis	Study design, manuscript revision, final approval of manuscript

Principal Supervisor Confirmation

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Glenn Gardner
Name

Signature

15/09/16
Date

4.4.1 Publication – Study protocol

Open Access Protocol

BMJ Open

Effectiveness of an emergency nurse practitioner service for adults presenting to rural hospitals with chest pain: protocol for a multicentre, longitudinal nested cohort study

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Effectiveness of an emergency nurse practitioner service for adults presenting to rural hospitals with chest pain: protocol for a multicentre, longitudinal nested cohort study.

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Article first published online: 12 February 2015.

DOI 10.1136/bmjopen-2014-006997

BMJ Open 2015;**5**:e006997

Journal Metrics	
Impact factor	2.271
H index	24
SCImago Journal Rank (SJR)	1.13 Q1

Abstract

Introduction

Chest pain is common in emergency department (ED) patient presentations and management presents challenges for rural health services. Reforming health services to improve access to care calls for appropriately skilled and supported clinicians for the delivery of safe and effective care. Despite the increased use of emergency nurse practitioners (ENPs) as one step in addressing these reforms, little is known about the safety and quality of the service they provide in the rural ED context. The aims of this study are (1) to examine the safety and quality of the ENP service model in the provision of care in the rural environment and more specifically (2) to evaluate the effectiveness of the service in the management of patients presenting with undifferentiated chest pain.

Methods and analysis

This is a protocol for a prospective longitudinal nested cohort study to compare the effectiveness of ENP service with that of standard care. Adults presenting to three rural EDs in Queensland, Australia with a primary presenting complaint of atraumatic chest pain will be eligible for enrolment. We will measure (1) clinician's use of evidence-based guidelines (2) diagnostic accuracy of electrocardiograph interpretation for the management of patients with suspected or confirmed acute coronary syndrome (ACS) (3) service indicators of waiting times, length-of-stay and did-not-wait rates and (4) clinician's diagnostic accuracy as measured by rates of patient unplanned ED representation within seven-days (5) satisfaction with care, (6) quality-of-life and (7) functional status. To assess these outcomes, we will use a combination of measures collected from routinely collected data, medical record review and questionnaires (with 30-day follow-up).

Ethics and dissemination

Human Research Ethics Committee (HREC) of Queensland Health and Queensland University of Technology has approved this protocol. It is intended that protocol results will be published in peer-reviewed scientific journals and presented at scientific conferences.

Introduction

People living in rural areas have shorter lives and poorer health outcomes when compared to people living in major cities, are more likely to be overweight, lead sedentary lifestyles and engage in risky behaviours like smoking and drinking alcohol in harmful quantities (Australian Institute of Health and Welfare, n.d.). It is likely that a combination of inequity in access to health services, risk factors and the rural environment are responsible for poorer rural health outcomes (Australian Institute of Health and Welfare, n.d.).

Chest pain represents 5-10% of Australian annual emergency department (ED) presentations (George et al., 2013; Than et al., 2014) and is responsible for a quarter of all hospital admissions (Than et al., 2014). Chest pain is symptomatic of many presenting aetiologies, one of which is acute coronary syndrome (ACS). This classification encompasses a broad spectrum of clinical presentations that includes acute myocardial infarction through to a pattern of angina without evidence of damage to the heart muscle (Chew et al., 2011). Given that acute myocardial infarction is the leading cause of sudden death in the Australian population (Kinsman et al., 2012), undifferentiated chest pain is a presentation of significance in EDs.

Whilst chest pain is a characteristic of ACS, the majority of patients with chest pain are ultimately found to have non-cardiac diagnoses (Cullen et al., 2013; George et al., 2013; Groarke et al., 2013; Meek et al., 2012). Not-with-standing the diagnostic outcome, there is considerable cost to health services in evaluating patients who are experiencing undifferentiated chest pain. The challenge for clinicians and health services in caring for this patient cohort is to provide assessment and management with a high degree of safety in a timely and cost-effective manner in an era of increasing service demand (Parsonage et al., 2013). Strategies to reduce delays to testing, selection of patients for outpatient evaluation and assessment protocols that expedite evaluation and early specialist review are necessary (Groarke et al., 2013).

The rural context of care impacts on the capacity of health services to deliver care to patients presenting to EDs with chest pain. There are lower numbers of health care professionals in rural areas and most hospitals do not employ dedicated staff within the ED. Health service usage differs between major cities and rural locations due in part to the lower rates of general practitioner consultations and higher rates of hospital admissions (Australian Institute of Health and Welfare, n.d.). This has resulted in a call for rural health service reform to improve access by using an appropriately skilled and supported workforce in the delivery of quality care that is effective, appropriate and sustainable (Standing Council on Health of the Australian Health Ministers Conference, 2012a).

There are many examples of innovative health service models being implemented throughout Australia including the use of expanded roles in nursing with the introduction of nurse practitioners (NPs). NPs have specialist skills and practice in an advanced nursing role with legislated extensions to practice. The emergency nurse practitioner (ENP) service model is the fastest growing NP specialty group in Australia with 61% growth in numbers over a three-year period (Middleton et al., 2011). In rural Australian EDs, there is growing use of this service with 38% of these departments now staffed by ENPs (Barnason & Morris, 2011). Whilst the ENP model has been utilised in rural areas to meet the need for accessible, quality care, little is known about the safety and quality of the service in this context.

To date there is no indication of published research investigating the effectiveness of ENP service in the management of patients presenting with complex medical needs in the rural context. This planned study, "Managing Chest Pain in Rural Emergency Departments", will address the gap in research by providing knowledge on ENP service and the processes and outcomes of care for rural patients experiencing undifferentiated chest pain.

Methods and analysis

Study aims

The aim of this study is to examine the safety and quality of the ENP service model in provision of care in the rural environment and to evaluate the effectiveness of the service in the management of patients presenting with undifferentiated chest

pain. We plan to investigate several outcomes in order to address the following research questions:

- What are the health service structures that influence the ENP delivery of safe, quality care for patients presenting to rural EDs with chest pain?
- Are the processes of care for patients who present to rural EDs with chest pain equivalent for patients managed by an ENP service to those managed in the standard model of care?
- Are the comparative outcomes for patients who present to rural EDs with chest pain equivalent for patients managed by an ENP service to those managed in the standard model of care?

Study conceptual framework

Evaluation of the safety and quality of the use of ENPs as a service innovation calls for an approach that can accommodate the complexity of multiple dimensions of a service improvement initiative (Gardner et al., 2014). The Donabedian Framework (Donabedian, 1966) provides a model that supports systematic evaluation of health care services and will be used to guide data collection and inform interpretation of the study findings. According to Donabedian, there are three dimensions from which conclusions about the quality of care can be drawn; these are structure, process and outcome (Donabedian, 1966). *Structure* refers to the attributes of the health care setting (material, human and organisational resources), *Process* refers to what is actually done in the giving and receiving of health care and *Outcome* refers to the effects of health care on patients and populations (Donabedian, 1988) (See Figure 9). In essence the model asserts that quality in health care is possible because there is a relational effect; good structures increase the likelihood of good processes, which increases the likelihood of good outcomes. The framework is one of the best-known and widely used conceptual models for health services research (Lawson & Yazdany, 2012) and provides a basis for a rigorous, multidimensional evaluation of this service innovation. Examination of the structure of care for patients with chest pain who are managed by the ENP service is required to identify the limitations and advantages of this model of care. Evaluating the process and outcomes of care for the ENP service for this cohort of patients will assist in determining the quality of care provided. Further, by using a safety and quality

framework, the strengths and weaknesses of each of these components and the implications for the safety and quality of the service may be identified.

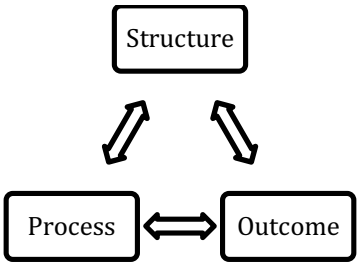

Figure 9 Donabedian's structure-process-outcome framework

Design

This project is a prospective multicentre longitudinal cohort study. The study cohort is defined as adult patients presenting with atraumatic chest pain. A cohort design was chosen for this study to allow for an evaluation of the service model that is inclusive of multiple dimensions including the structure, process and outcome of the service and its context. Although randomised controlled trials are considered the "gold standard" for research, in the area of healthcare, they cannot always be easily conducted (Hood, 2009; Silverman, 2009). RCTs are not always suited to evaluating complex combinations of service interventions and practices in terms of their real world effectiveness (Horn & Gassaway, 2007; Soh & Saw, 2010) in the context of a safety and quality framework. By using a cohort design, a specific population (rather than an isolated intervention or treatment) can be studied using multiple outcomes related to one or more exposures (Hood, 2009; Soh & Saw, 2010). Additionally, a nested cohort will be identified from the study cohort and will consist of patients with International Classification of Diseases discharge diagnoses codes I20-I25 from the group ischaemic heart diseases (World Health Organisation, 2016). Specific diagnoses may include, but are not limited to, possible cardiac chest pain, angina pectoris, acute coronary syndrome and myocardial infarction. Using this nested cohort allows for statistically efficient analysis of data with substantial time savings (Hood, 2009).

Independent Variable

The independent variable is the service model involved in the management of patients presenting with undifferentiated chest pain. For the purpose of this study the models are operationally defined as follows:

- Emergency nurse practitioner model: The ENP manages the patient presenting with undifferentiated chest pain. The ENP delivers and coordinated care in the diagnosis, investigation, therapeutic treatment (including prescribing of medications and technical interventions) and referral. In this model ED nursing staff work with the ENP in providing nursing care to the patient.
- Standard care model: In this traditional model, all care for the patient presenting with undifferentiated chest pain is delivered and coordinated by a medical officer. In this model ED nursing staff work with the medical officer in providing nursing care to the patient.

In both models all clinicians work collaboratively and within their designated scope of practice.

Outcome Variables

Outcome measures take into account the Donabedian SPO Framework. To assess the effectiveness of ENP service in the management of patients presenting to rural EDs with undifferentiated chest pain, we will measure and compare with standard care the following outcomes:

1 Use of evidence-based guidelines for the management of patients with suspected acute coronary syndrome *(Nested cohort) (Primary outcome variable)*

2 Diagnostic accuracy of electrocardiograph interpretation *(Nested cohort)*

3 Service indicators of waiting times, length-of-stay and did-not-wait rates *(Study cohort)*

4 Diagnostic accuracy as measured by rates of unplanned representation within seven-days *(Study cohort)*

5 Satisfaction with care *(Study cohort)*

6 Quality-of-life *(Study cohort)*; and

7 Functional status *(Study cohort)*.

The extraneous variable for this study is ENP service; outcomes will assess the structural characteristics of the model, including:

1 Barriers and facilitators for ENP practice

2 Professional characteristics (years of experience)

3 Psychosocial characteristics (perceived role competence)

Setting

The study will take place in three rural hospital EDs, of differing size, in Queensland, Australia. There are approximately 26 000 ED presentations yearly for Hospital A, 21 000 for Hospital B and 8 000 for Hospital C. These EDs have similar service capabilities including staff mix, available health technologies and referral strategies. Both onsite doctors and ENPs staff each facility. There are varying levels of experience in the medical and ENP staff that includes newly qualified staff through to veteran clinicians. Furthermore, all sites have both ENP service and standard medical care for the management of patients presenting with undifferentiated chest pain. There are no specialist cardiac services at any of these EDs and each facility is located more than 150 km from the closest cardiac interventional hospital. Collaborative arrangements with specialist medical services for consultation and acute interhospital transfer are similar for medical and ENP service at each facility.

As this research is an observational study, there will be no allocation of intervention; rather the care delivery model will follow the standard method of patient allocation. The current practice at these facilities involves the use of the Australasian Triage Scale to ensure that patients are treated in order of clinical urgency. The next available clinician (ENP or medical officer) is responsible for providing care to patients in order of clinical urgency. Medical and ENP service is provided in and out of hours.

Participants

Inclusion criteria

Patients who present to the ED with chest pain to participating EDs during the data collection period will be eligible for recruitment, if they:

1. Are at least 18-years old;
2. Have chest pain that is not the result of an acute injury;
3. Are capable (or have a legally acceptable representative) of providing informed consent.

Participant Recruitment

There are two participant groups in the study; ENPs and patients.

ENP recruitment will be conducted at the start of the study. ENPs from each participating site will be invited to participate and supplied with study information and consent documents. On providing informed consent, ENPs will be requested to complete a self-administered questionnaire.

Patient recruitment will commence in November 2014 and will continue through until May 2015. At the index presentation, presenting patients who meet the inclusion criteria will be identified by the triage nurse or the treating clinician and invited to participate in the study. Participation in this research will involve the completion of a patient questionnaire at baseline, the researcher's use of routinely collected data and completion of follow-up patient questionnaire. Potential participants will receive information and consent package, explaining the purpose of the research and procedures involved in completing the study. Trained research assistants will explain the study, enrol eligible consenting patients and assist with the completion of a baseline questionnaire. Patients will be advised that they may decline to engage in the study or withdraw from participation at any time without disadvantage.

Data will be collected at the ED where patients are seeking care for their acute chest pain. While it is envisaged the majority of patients will be able to provide consent, some may be critically unwell and initially lack capacity to provide informed consent because of the emergent nature of their illness. Where a lack of capacity is deemed to be temporary and is expected to resolve in the course of

treatment, consent will be sought from a legally acceptable representative (including the patient's relatives). When the patient recovers capacity, the patient will confirm consent (or not) as soon as practicable after the initial emergency has passed. If once the patient has regained capacity he/she withholds consent then that patient and their data will be withdrawn from the study.

Data collection

After informed consent is obtained, baseline data regarding demographic and clinical data will be collected for the *study cohort*. Minimal demographic data will be collected on patients who decline to participate to allow comparison to evaluate the homogeneity of the study sample. Baseline data collected will be used for several purposes. First, demographic data will be used to collect information on potential patient confounders that are required for statistical analysis. Second, using the diagnosis assigned by the treating clinician as determined at the time of discharge from the ED, patients will be identified for inclusion in the nested cohort. Data for the *nested cohort* will be collected from the medical record.

At the completion of the occasion-of-service, all study participants will be requested to complete a self-administered questionnaire that will measure patient-reported outcomes including satisfaction, quality-of-life and functional status. Data for unplanned representations to the ED will be collected seven-days after the index presentation.

Follow-up questionnaires will be posted to all study participants at 30-days after the index ED presentation.

The flow diagram for patient recruitment and data collection during the study is provided in Figure 10.

Instruments

This research will use a variety of methods to assess study outcomes including the use of routinely collected demographic and clinical data, medical record review and questionnaires (see Table 9). To ensure reliable and unbiased extraction of data from the medical record review, research assistants will be trained in the use of data abstraction tools that have been designed for this study.

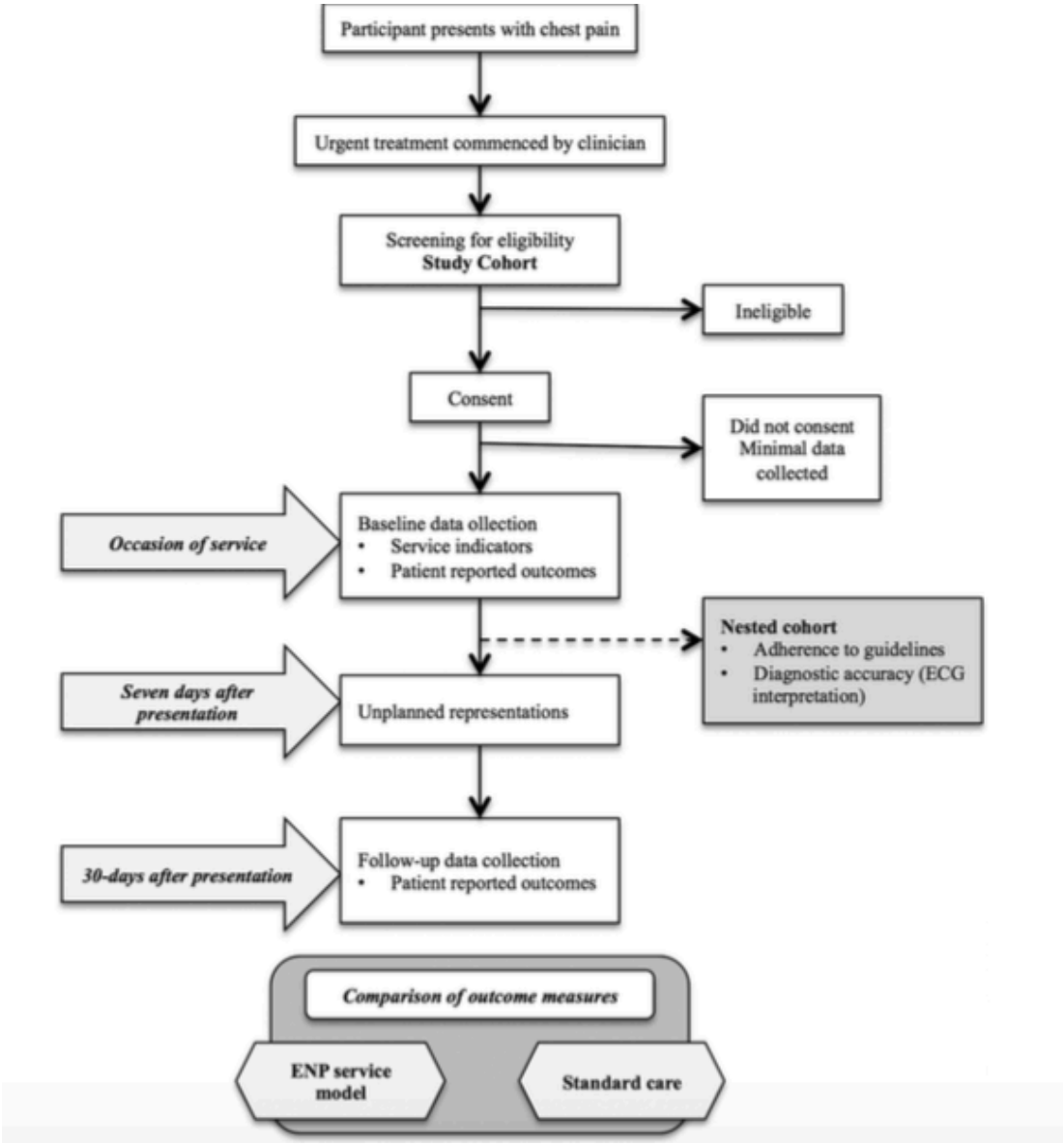

Figure 10 Flow diagram for patient recruitment and data collection.

Table 9 Quantitative data collected at each time period

Time period*	Data source	Data collected
Commencement of study	ENP questionnaire	Structural characteristics of the service
Baseline	Patient questionnaire	Demographic data Patient-reported outcomes
	Medical record	Clinical data
	Routinely-collected data	Service indicators
Seven-days	Routinely-collected data	Unplanned representations
30-days	Patient questionnaire	Patient-reported outcomes

*Time period (in relation to the patient's ED presentation) from which data will be collected

ENP questionnaire: A self-administered questionnaire of participating ENPs will be used to evaluate the structural characteristics of the service that are perceived barriers or enablers to practice. The questionnaire uses a component of the National Nurse Practitioner Survey that was developed in the Australian Nurse Practitioner Study (AusPrac) (Gardner, Gardner, Middleton, & Della, 2010).

Baseline patient-reported outcomes questionnaire: This study will use an adaptation of the patient outcomes tools that were developed and/or incorporated from published work for the AusPrac Study (Gardner et al., 2010). With permission of the authors, this study will adapt the AusPrac patient outcomes scales to assess patient satisfaction, experience with coordination of care, quality of life and functional status. Functional health and well-being will be measured using the SF-12®, a copyrighted instrument of QualityMetric Incorporated (QualityMetric, n.d.). Internationally, the SF-12 survey has demonstrated reliability and validity (Snellman, Jonsson, & Wikblad, 2012; Ware, Kosinski, & Keller, 1996), including in Australia (Fisher, 1999; Sanderson & Andrews, 2002). The instrument has been used previously for investigation of patients with non-cardiac chest pain (Cheung et al., 2009) and for patients managed by the ENP service in Australia (Dinh et al., 2012; Gardner et al., 2010). Permission to use this instrument for the study has been provided by the copyright holder.

Follow-up patient-reported outcomes questionnaire: These questionnaires will assess patient-reported outcomes using the modified AusPrac patient outcome scales and the SF-12®.

Data abstraction tool for study cohort: A tool that utilises routinely collected data has been developed for the study. Data collected includes Australasian Triage Score,

treating clinician category, diagnosis at discharge and discharge destination, service indicators including waiting time, length-of-stay, did-not-wait and unplanned representations will also be collected.

Data abstraction tool for nested cohort: Data will be collected from the participant's medical record using a tool that has been designed for the study. The tool uses criteria from the Clinical Pathway currently in use in Queensland Health facilities (see Appendix E). These clinical pathways are used in all participating study sites and are based upon the best practice recommendations of the National Heart Foundation/Cardiac Society of Australia and New Zealand Guidelines for suspected or confirmed acute coronary syndromes (Chew et al., 2011). Data will be collected to evaluate clinician's adherence to evidence-based guidelines, including pharmacological management, risk stratification and referral strategies. Where data is missing from the medical record (e.g., evidence of administration of aspirin is not recorded) the intervention will be assumed not to have occurred. For the purposes of this study, cardiac biomarker testing that occurs at any time during the ED stay will be assessed as being 'on arrival' and in accordance with current guidelines. A copy of the participant's ECG/s will be collected. A blinded assessor who has specialist qualifications in emergency medicine will examine the treating clinician's interpretation of the diagnostic ECG for diagnostic accuracy.

Sample size calculation

There are an estimated 4,730 total ED presentations across all participating sites each month. According to findings from a previous study (Roche et al., 2014), undifferentiated chest pain made up 3.5% of these and 39% of this group were cardiac related. Using these findings, there are approximately 65 patients with cardiac related chest pain presenting to each of the participating EDs per month. Therefore, in order to achieve the requisite sample, recruitment will be conducted over a six-month period.

The sample size calculations were based on 80% power and a type I error rate (two-sided) of 0.05. Sample size estimation was calculated for the nested cohort that will be used to evaluate the primary outcome of use of evidence based guidelines for patients with cardiac-related chest pain. This calculation was based on 1) perusal of prior research studies together with unpublished local data to determine the rate of

protocol compliance expected in cardiac chest pain patients at an estimated 50%, 2) the proportion of cardiac chest pain patients who were seen by ENPs was identified as 25% and 3) the difference in protocol compliance between ENPs and doctors is expected to be larger than 20%. The sample size calculated for the primary outcome cohort study under these assumptions is 384 patients with cardiac related chest pain with an odds ratio of 2.25.

Data analysis

The conventional 5% level of statistical significance will be used. All analyses will be conducted using de-identified patient data using SPSS software (IBM SPSS Statistics) V.22.

- *Structural characteristics of the ENP service model:* Descriptive statistics will be used to summarise the data for structural characteristics of the ENP service model. Categorical data will be displayed as a proportion for each of the components of the survey.
- *Patient Demographic and clinical data:* Baseline characteristics potentially associated with study outcomes (age, gender, education level, employment, ATSI status, previous health service usage) will be reported separately for each service model. The data collected will be analysed using descriptive statistics. Dichotomous and nominal data will be displayed as a proportion; comparison of clinical data will be examined and tested for significance using the chi-square test.
- *Service indicators and unplanned representation within 7 days:* Descriptive statistics will be used. Continuous data will be used for analysis of waiting times and length-of-stay. Normally distributed data will report means and standard deviations; comparisons between service models will be examined using the unpaired t-test. Data not normally distributed will be analysed using medians and IQR; comparisons between the two models will be tested for statistical significance using the Mann-Whitney test. The dichotomous data for unplanned representations will be displayed as an odds-ratio (OR); comparison between the service models will be examined and tested for significance using the chi-square test.

- *Adherence to evidence-based guidelines:* Descriptive statistics will be used to summarise the adherence to guidelines for patients with suspected or confirmed ACS. A blinded assessor who has specialist qualifications in emergency medicine will undertake independent interpretation of ECGs, which will be compared to the clinician's interpretation. Dichotomous data will be displayed as a percentage of agreement proportion; comparisons between the service models will be examined and tested for significance using McNemar's test.

- *Patient-reported outcomes:* Data will be summarized and measures of distribution for patient-reported health outcomes will be conducted. Nominal and ordinal data collected for analysis of patient satisfaction will be displayed as a proportion; comparisons between the two service models will be examined and tested for significance using the chi-square test. The data for the SF-12® summary scores will be managed and analysed according to the guidelines from the SF tools and will be reported using means and standard deviations (for normally distributed data) or medians and IQR (for not normally distributed data). Comparisons between the service models will be tested for statistical significance. Regression analyses will evaluate the associations between functional status and other influencing factors.

Ethics and Dissemination

Standard procedures for the protection of confidential individual information will be followed in accordance with national and international ethical recommendations and guidelines as well as relevant legislation.

The results of this study provide evidence of the safety and quality of the ENP service model. The findings will be disseminated locally to inform health service planning and future recommendations for practice. Manuscripts arising from the study results will be submitted to peer-reviewed scientific journals and conference presentations will be prepared for both Australian and international conferences

Discussion

Studies supporting the use of ENP service are mostly conducted in the context of minor injury and illness presentations and in metropolitan settings. Beyond this context, the safety and quality of ENP service is not well researched and is poorly understood. We have described the protocol for a longitudinal nested cohort study,

The Managing Chest Pain in Rural Emergency Departments, which will examine the effectiveness of ENP service in the management of patients presenting to rural EDs with undifferentiated chest pain. This study is one of the first to evaluate rural ENP service in the management of a higher acuity, time sensitive presentation like chest pain.

Although RCTs are considered the 'gold standard' for research, a cohort design was chosen for this study because the guiding framework necessitates an evaluation of the service model that is inclusive of multiple dimensions that could not easily or ethically be conducted in this setting. Selection bias will be minimised by the use of a clearly defined study population and inclusion criteria. The study has been designed to avoid losses to follow-up and is conducted over a relatively short period of time. Information bias has been avoided by the use of clear, specific, measurable outcomes that will be accurately and consistently measured. The study will combine detailed information from routinely collected data, participants' medical record and questionnaire with repeated follow-up measurement from patients presenting to rural EDs with chest pain. Questionnaires have been developed using validated scales and tools.

Examination of the clinical care provided for this cohort of patients will contribute to the understanding of processes and outcomes for patients presenting to rural hospitals with undifferentiated chest pain. Using a longitudinal approach, the study will provide knowledge on both the management of patients presenting to rural EDs with chest pain and the effectiveness of ENP service in the rural context.

A potential limitation of the study is that although the study is powered to demonstrate statistically significant differences between service models, the ENP sample size is small and may affect the generalisability and external validity of the results of this study.

In conclusion, whilst the timely delivery of quality patient care in the ED has emerged as one of the most important service indicators to be measured in contemporary health care, there are significant gaps in the research that has evaluated ENP service on the outcomes and processes of care for patients. Despite the increasing use of ENPs in rural areas, there is scant research reported in the national and international literature regarding ENPs in the rural emergency department.

There is also a scarcity of research that has evaluated the model outside of the minor injury and illness context. The management of patients presenting to rural EDs with chest pain is under researched and poorly reported the literature. This research will provide new information specific to this service and will assist in providing an evidence base for this innovation at a level that has not been studied before.

Contributors. TER conceived and designed the study with GG and PAL. TER wrote the manuscript, and GG and PAL revised it critically for important intellectual content. All authors approved the final manuscript.

Competing interest. None

Ethics approval. Ethical approval for the study has been granted by Queensland Health Human Research Ethics Committee (reference HREC/13/QHC/30) and the Queensland University of Technology Human Research Ethics Committee (reference: 14000000709).

END OF PUBLISHED MANUSCRIPT

References for the published manuscript are included in the thesis reference list

4.5 MODELS OF CARE

The previous manuscript briefly introduced the independent variable for the study; that is, the service model that was involved in the management of patients presenting with undifferentiated chest pain. For the study purpose, the models were operationally defined as: (i) emergency nurse practitioner model, or; (ii) standard care model. This section of the Chapter will provide more detail about the clinical capacity of each of the models and discuss the differences between the models.

4.5.1 Emergency nurse practitioner model

Nurse practitioners in Australian emergency departments provide complete occasions of service within Board defined and individually agreed NP scope of practice that is influenced by the context of the care setting, the health needs of the community and the confidence and competence of the individual NP (College of Emergency Nursing Australasia, 2015).

The rural ENP has been reported as practicing autonomously or in collaboration with rural doctors (Roberts, 1996). In the autonomous mode the ENP makes clinical decisions regarding the patients care, with practice equivalent to that of medical colleagues. The ENP decides when medical collaboration is required and in emergencies, the ENP makes decisions that are usually the domain of the medical practitioner (Roberts, 1996).

For the participating study sites, the ENP service model was well-established with a scope of practice that includes the management of high acuity patients including those with chest pain. The ENP model was involved in the assessment and management of patients presenting with undifferentiated chest pain, including referral to other health care professionals, prescribing of medication, performing interventions, ordering and interpreting diagnostic investigations.

4.5.2 Standard care model

This was the traditional model of care, in which care was delivered or coordinated by a medical officer for patients presenting with undifferentiated chest pain. For each site there are varying levels of experience for the medical officers, with no single medical officer possessing specialist skills in emergency medicine.

For both service models, clinicians work within their scope of practice and collaboration with other health care professionals (either internally or externally) occurs as required.

4.6 DATA MANAGEMENT

The protocol reported information on data collected in the study; however due to the word limitation requirements of publishing, this information was limited. Accordingly, this section of the Chapter will discuss in detail the instruments used for this study and the training and roles of research assistants.

4.6.1 Instruments

This research used a variety of methods to assess study outcomes including the use of routinely collected demographic and clinical data, medical record review and patient survey (see Table 10).

<u>Adherence to clinical pathways (Primary outcome variable)</u>

The study evaluated clinicians' adherence to clinical pathways, including diagnostic investigations, pharmacological intervention and referral strategy, through medical record review using a data abstraction tool specially designed for this study. Clinical pathways developed from evidence-based guidelines are implemented to reduce variability in clinical practice in order to improve patient outcomes. In Queensland Health, clinical pathways for the management of patients presenting to either interventional or non-interventional EDs is recommended (Queensland Health Clinical Access & Redesign Unit) (see Appendix E). These clinical pathways were used in all participating study sites and are based upon the best-practice recommendations of the National Heart Foundation/Cardiac Society of Australia and New Zealand Guidelines (Chew et al., 2011).

Demographic and clinical data

Demographic data were collected to ascertain the baseline characteristics of the cohort. These data were sourced from a patient questionnaire of consenting patients that formed part of enrolment procedures at time of presentation to ED. A standardised tool that conformed to recommendations (Australian Institute of Health and Welfare, n.d.) for consistency of data collection and reporting was used. Demographic data included age, gender, employment status, Aboriginal and Torres Strait Islander status, country of birth, employment and education. Clinical data included Australasian Triage Score (ATS), treating clinician category, diagnosis at discharge and discharge destination was recorded using routinely collected data from EDIS at the completion of the occasion-of-service.

Table 10 Rural chest pain study variable measurement and instruments

		Indicator	*Data collection method*
Primary outcome variable	Use of evidence based guidelines	Measurement of level of adherence	Medical record review using data abstraction tool
	Diagnostic accuracy	Accuracy of ECG interpretation	Blinded assessor
Secondary outcome variable	Service indicators	Measurement of a) Waiting times b) Length-of-stay c) Did-not-wait	Emergency Department Information System
	Unplanned representations	Measurement of representations within 48-hours	Emergency Department Information System
	Patient-reported outcomes	Measurement of	
		a) Satisfaction with care	AusPrac tool
		b) Quality-of-life	AusPrac tool
		c) Functional status	SF-12 ®
Extraneous variable	Structural characteristics of ENP service	Measurement of a) Barriers and facilitators b) Professional characteristics c) Psychosocial characteristics	AusPrac tool

Service indicators and unplanned representations within seven-days

Routinely collected data were used to evaluate the secondary outcome variables of service indicators including waiting time, LOS, DNW and unplanned representations.

- **Waiting time** was defined as the time in minutes from initial assessment by the triage nurse until the treating clinician for that patient was registered in EDIS.
- **Length-of-stay** was defined as the time in minutes from initial registration until the time of the patients' "ready" for departure from the ED as recorded in EDIS. The triage nurse on the patients' arrival assigned the ATS after

initial assessment to the ED. This study included patients from any ATS category, with wait time service standards ranging from immediate to two-hours for treatment to be commenced by the clinician (Australasian College of Emergency Medicine, 2002).

- **Unplanned representation within seven-days** was identified by review of EDIS seven-days after the initial presentation for all participants who were recruited to the study. Participants whose visit type was recorded as "unplanned representation" based on triage nurse clinical decision were identified.

  A recent study of ED discharges (n = 4 782 045) was conducted to assess the time to an ED revisit (Rising, Victor, Hollander, Carr, & Griffey, 2014). These researchers noted although there was limited explanation as to the rationale for the use of any specific time period, prior studies used three different times periods for ED revisits: 2 to 3, 7 to 8 or 30-days. Three days was identified as not being long enough to capture unplanned representation, with less than 30% of unplanned representations not being identified in this time frame. Using statistical modeling a "hinge point" of 9-days was identified to represent a transition from "early" to "late" representations. The early return presentation population included patients for whom there were problems with the discharge process or outpatient treatment plan whilst the late return presentation population was characterized by patients with reasons that may not be related to the prior visit.

  Taking these findings into consideration, combined with a requirement for homogeneity with other studies, this study designated a seven-day time frame for unplanned representation.

Patient-reported health outcomes

The research examined patient-reported outcomes as a secondary outcome variable for the research. These measures were designed to collect data on the patient's perceptions of outcomes related to the quality of health care. Two tested and validated tools were used to develop a questionnaire that was completed by participants at the emergency department occasion-of-service. Follow-up

questionnaires were posted to all study participants at 30-days after the initial emergency department presentation.

The first tool used was a modified Ausprac patient outcomes scale (Gardner et al., 2010) that incorporated multiple validated and tested tools. We used the components of satisfaction with care, that was derived from two sources (Allnut et al., 2010; Safran, 2002), coordination with care (Safran, 2002) and level of health service utilisation (Stanford Patient Education Research Centre, n.d.).

The second tool used was the SF-12® survey (QualityMetric, n.d.) to measure quality-of-life and functional status. The tool contains 12 items that are used to construct physical component summary (PCS) and the mental component summary (MCS) scores. The SF-12 has demonstrated reliability and validity (Snellman et al., 2012; Ware et al., 1996), including in Australia (Fisher, 1999; Sanderson & Andrews, 2002). The instrument has been used previously for investigation of patients with non-cardiac chest pain (Cheung et al., 2009) and for patients managed by the ENP service in Australia (Dinh et al., 2012).

Structural characteristics of the ENP service model

The study examined the structural characteristics of the ENP service model as an extraneous variable. A self-administered survey was completed by the ENP in each participating ED at the commencement of the study. was used to evaluate the. The tool included items related structural characteristics that were identified as barriers or enablers to practice, as well as the professional (years of experience) and psychosocial (perceived level of competence) characteristics of the ENP. The questionnaire used a component of the National Nurse Practitioner Survey (Gardner et al., 2010), an instrument that was used in two previous national nurse practitioner censuses (Gardner, Gardner, Middleton, & Della, 2009; Middleton et al., 2011).

4.6.2 Clinical and outcome research assistants

The rural health services that participated in the study offer extended placements for medical students. These students were invited to participate as assistants in the research project. Nurses working in the ED were also identified as being potential research assistants. A flyer was sent out to each of the participating sites inviting expressions of interest to be included in the research team. The Research Assistant protocol was developed prior to the commencement of the

proposed study (See Appendix H). The lead researcher (the PhD candidate) spent one-week at each participating site to train and prepared a team to participate as clinical research assistants (CRA) or outcome research assistants (ORA) for the various stages of the study. The aim of this clear delineation of the CRA and ORA roles was to reduce bias that may occur in the recruitment and data management phase of the research. Training of research assistants included a presentation outlining the research methods and aims. The research assistants were trained in methods of consent, data collection and the procedure for the transfer of study data to the Lead Researcher. Once training was completed, all research assistants were teamed with the lead researcher to observe precision of recruitment and data collection processes. From the three participating sites, a total of 32 research assistants participated in this training.

The CRA's recruited patients, collected baseline data and maintained a database for both the study and the nested cohort of patients. The CRA's provided patients with the study information and consent documents prior to inviting them to participate in the study. The CRA was trained in the assessment of patient's capacity to provide consent or in the identification of a suitable surrogate decision-maker for the patient. The CRA conducted the informed consent discussion and checked that the patient, and/or their legally acceptable representative comprehended the information provided. The CRA answered any questions from the patient and/or the patient's surrogate decision-maker regarding the study. Clinical data regarding the ED presentation was collected (using the data abstraction tool, see Appendix F) and entered into the study database by the CRA on completion of the occasion-of-service. The demographic data from the patient enrolment survey was entered into a database that was maintained by the CRA. Patients recruited to the study were provided with the patient questionnaire by the CRA at the occasion-of-service. The CRA maintained a database of patients and subsequently ensured that the follow-up patient questionnaire was mailed to participants at the 30-day interval.

The ORA's collected data regarding the participants' ED occasion of service. Using the data abstraction sheet for the study cohort the ORA collected data from EDIS for measurement of service indicators including waiting times, length-of-stay, Did-Not-Wait and unplanned representations. The ORA reviewed the patient's discharge diagnosis and assigned eligible patients to the nested cohort. For patients

allocated to the nested cohort the ORA used the medical record to collect data regarding the use of evidence-based guidelines using the data abstraction tool for the nested cohort (see Appendix G).

4.7 BIAS AND CONFOUNDING

Without true experiment conditions it is difficult to avoid bias completely. It is however, possible to minimise the effects and improve the rigour of observational studies by seeking out and eliminating potential biases as early in the study as possible (Healy & Devane, 2011). For cohort studies, the main sources of bias arise from selection bias and information bias (Grimes & Schulz, 2002; Healy & Devane, 2011).

In this research selection bias was minimised by the use of a clearly defined study population and clear inclusion and exclusion criteria that were uniformly applied. The allocation of patient participants to either model of care occurred in the same ways according to established practices at each participating site. Data were obtained on losses to follow up and analysed to observe if selection bias occurred by assessing for differences in the baseline characteristics of the participants. Strategies to maximise response rates were used including telephone follow up and reminder letters. Information bias was avoided by the use of clear, specific, measurable outcomes that have been defined in advance and with the use of validated tools. Accurate and consistent measurement of outcomes was performed in the same manner, using the same data abstraction instruments, for both the exposed and non-exposed groups (see Appendices F and G). Potential confounders for this research include both clinician and patient variables. Clinician variables included experience and practice scope, and patient variables included age, gender, education level, employment, ATSI status and previous health service. To maximise the rigour of this study, data were collected on these confounders and were controlled for in the statistical model.

4.8 ETHICAL CONSIDERATIONS

The STROBE guidelines for reporting observational studies (von Elm et al., 2008) are used to facilitate adequate reporting of the study results to allow the assessment of strengths and weaknesses and the studies' generalisability. The research conforms to the provisions of the Declaration of Helsinki in 1995 (as

revised in Tokyo 2004) and was conducted according to the principles for ethical conduct in human research as articulated by the National Health and Medical Research Council of Australia (2007). All participants in the research are protected by the principles of confidentiality. Full disclosure of the research and the opportunity to consent to be included in the study were provided to all eligible patients. Patients could decline to engage in the study or withdraw from participation at any time without disadvantage.

All data collected has and will continue to be securely stored using both physical or electronic methods appropriate to the data (locked filing cabinet or password-protected database). Data will be retained for a minimum of five-years after the publication of results.

An application for the proposed study was submitted to both the QUT Human Research Ethics Committee and Queensland Health Human Research Ethics Committee. Approval was granted by these committees prior to undertaking any recruitment or data collection for the research (See Appendices N and O).

Data were collected at the ED where patients presented seeking care for acute chest pain. An ethical challenge for this research was that potential participants may be critically unwell and may initially lack capacity to provide informed consent, or the ability to complete a written informed consent form, yet the very nature of this research required that recruitment takes place quickly in the emergency setting and included acutely unwell patients. Respecting the need for patients' need to be assessed, diagnosed and treated for their acute illness, the patients were treated according to standard clinical routines at the ED. Contact with the treating clinician was never delayed because of recruitment or data collection.

While the majority of patients were able to provide witnessed verbal or written consent, a minority of patients may not have had the initial capacity to provide informed consent because of the emergent nature of their illness. Where this capacity was deemed to be temporary and was expected to resolve throughout the course of treatment, consent and agreement was obtained from a legally acceptable representative (including the patient's relatives). When the patient recovered capacity, the patient confirmed consent as soon as practicable after the initial emergency had passed. If once the patient regained capacity and he/she withheld

consent, the patient and their data was withdrawn from the study. In the case of patients who lacked capacity to consent and where no relative was available, the patient was not considered for inclusion in this study. Eligible participants who were able to give verbal consent, but who were unable to sign the consent form were recorded on the consent form as having provided verbal witnessed consent. Subsequent written consent for continuation in the study was sought as soon as possible after recruitment.

4.9 SUMMARY

The literature review presented in Chapter 2 provided evidence to support the use of an ENP service. Despite the recent growth and evolution of ENP service there was a paucity of high quality studies that evaluated the service beyond the scope of minor injury and illness. No study that evaluated rural ENP service was identified for inclusion in the literature review. Inquiry into ENP service necessitates a shift away from retrospective, qualitative research to provide evidence of the effectiveness of the service to develop and sustain the ENP role into the future. The conceptual framework described in Chapter 3 highlighted that in order to gain further knowledge about the safety and quality of the service in the management of complex conditions in the rural setting, research was required to examine the structural issues, the processes of care and the effectiveness of ENP service.

This well-designed observational research was the first to evaluate the safety and quality of ENP service in terms of patient satisfaction and clinical and organisational effectiveness in the provision of care to patients with complex health care needs. An observational prospective longitudinal nested cohort was chosen for this study for a number of reasons. Firstly, the study aimed to evaluate an established ENP service in the management of an urgent health complaint which precluded an RCT design being ethically conducted. In addition, the conceptual framework dictated a study design that included the evaluation of multiple dimensions not able to be easily studied using an RCT. Finally, the prospective cohort design was considered the strongest in minimising bias and other threats to validity and enabled the utilisation of a nested cohort.

This study protocol provides an example for researchers considering an observational study for health services research, particularly ENP service. By

publishing the protocol, this study was granted external review prior to its commencement and an awareness of the research was generated. Publication of the protocol also promotes transparency, openness and reproducibility of the study results which strengthens the validity of the study.

Chapter 5: Results

5.1 INTRODUCTION

The methodological approach adopted in this research was able to accommodate examination of a health services reform initiative in the rural ED for the management of patients presenting with a complex health condition. This Chapter presents the findings of the **Ma**naging chest **P**ain in **R**ural **E**mergency **D**epartments study. As demonstrated in the previous Chapter, the prospective nested cohort study was designed to accommodate an established service model and included strategies to avoid bias and manage confounders. The previous Chapter not only reported the study methodology but also reported the sample size calculation for the study. To summarise, in order to have sufficient statistical power to make inferences about the quality of care for the primary outcome a sample of 384 participants was required. Using the results of the preliminary study reported in Chapter 3, that provided new knowledge on the characteristics and outcomes for rural patients with chest pain, it was projected that the necessary sample size would be recruited to the study in a six-month period. In spite of extending this timeframe and the use of strategies to increase recruitment, only 61 participants were able to be recruited to the study. In this event, the study was inconclusive and underpowered to make conclusions about similarities or differences in the quality of care provided by the service models. The critical issues and problems that were encountered which led to a small sample size will be discussed in depth in the following Chapter.

A manuscript reporting the results from this study that has been submitted to *BMC Health Services Research* is provided. To reduce publication bias and improve reproducibility, the protocol for this study was previously published (see Chapter 4), providing a detailed account of the data analysis plan; data was analysed and reported as per this published study protocol. This approach ensures transparency by allowing readers to compare what was originally intended with what was actually done and makes data available for meta-analysis, which may in turn reduce distortion of the evidence from publication bias that emerges when published trials do not represent all trials undertaken (Schulz & Grimes, 2005). Secondly, using the planned data analysis and reporting method strengths the methodological quality of the study

by using statistical methods that were decided *a priori*. As part of the author submission guidelines for this journal, this study was retrospectively registered with the Australian New Zealand Clinical Trials Register (ACTRN12616000823471) (see Appendix K). A completed STROBE statement – checklist for of items required in reports of cohort studies is included at Appendix L.

Next, in alignment with the Donabedian framework introduced previously, the Chapter presents the data that were examined to evaluate the structural characteristics of the ENP service. The Chapter concludes by summarising the results of the study.

5.1.1 Missing data

There were small amounts of missing data for the sample that were isolated to responses from the patient-reported questionnaires; both at the occasion-of-service and follow-up evaluation. Analysis was performed using only available data.

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Statement of Contribution of Co-Authors for Thesis by Published Paper

The following is the format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified* that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the QUT ePrints database consistent with any limitations set by publisher requirements.

In the case of this chapter:

The effectiveness of emergency nurse practitioner service in the management of patients presenting to rural hospitals with chest pain: a multisite prospective longitudinal nested cohort study.

Submitted to *BMC Health Services Research* July 2016

Contributor	Statement of contribution*
Tina Roche 15/09/16	Study design, manuscript preparation, final approval of manuscript
Glenn Gardner	Study design, manuscript revision, final approval of manuscript
Leanne Jack	Manuscript revision, final approval of manuscript

Principal Supervisor Confirmation

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Glenn Gardner
Name

Signature

15/09/16
Date

5.1.2 Publication – Study results

The effectiveness of emergency nurse practitioner service in the management of patients presenting to rural hospitals with chest pain: a multisite prospective longitudinal nested cohort study.

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Submitted to *BMC Health Services Research* July 2016

Journal Metrics	
Impact factor	1.71
H index	64
SCImago Journal Rank (SJR)	1.13 Q1

Abstract

Background**:** Health reforms in service improvement have included the use of nurse practitioners. In rural emergency departments, nurse practitioners work to the full scope of their expanded role across all patient acuities including those presenting with undifferentiated chest pain. Currently, there is a paucity of evidence regarding the effectiveness of emergency nurse practitioner service in rural emergency departments. Inquiry into the safety and quality of the service, particularly with regard to the management of complex conditions is a priority to ensure that this service improvement model meets health care needs of rural communities.

Methods: This study used a prospective, longitudinal nested cohort study of rural emergency departments in Queensland, Australia. Sixty-one consecutive adult

patients with chest pain who presented between November 2014 and February 2016 were recruited into the study cohort. A nested cohort of 41 participants with suspected or confirmed acute coronary syndrome were identified. The primary outcome was adherence to guidelines and diagnostic accuracy of electrocardiograph interpretation for the nested cohort. Secondary outcomes included service indicators of waiting times, diagnostic accuracy as measured by unplanned representation rates, satisfaction with care, quality-of-life, and functional status. Data were examined and compared for differences for participants managed by emergency nurse practitioners and those managed in the standard model of care.

Results: The median waiting time was 8.0 minutes (IQR 20) and length-of-stay was 100.0 minutes (IQR 64). Participants were 2.4 times more likely to have an unplanned representation if managed by the standard service model. The majority of participants (91.5%) were highly satisfied with the care that they received, which was maintained at 30-day follow-up measurement. In the evaluation quality of life and functional status, summary scores for the SF-12 were comparable with previous studies. No differences were demonstrated between service models.

Conclusions**:** There was a high level of adherence to clinical guidelines for the emergency nurse practitioner service model and a concomitant high level of diagnostic accuracy. Nurse practitioner service demonstrated comparable effectiveness to that of the standard care model in the evaluation of the service indicators and patient reported outcomes. These findings provide a foundation for the beginning evaluation of rural emergency nurse practitioner service in the delivery of safe and effective beyond the setting of minor injury and illness presentations.

Trial registration**:** Australian New Zealand Clinical Trials Registry, ACTRN12616000823471 (Retrospectively registered)

Keywords: rural health services, chest pain, emergency treatment, patient satisfaction, quality of care, quality of life, nested cohort, cohort, nurse practitioner, adherence to guidelines

Background

Health inequalities for people living in rural communities are well reported (Australian Institute of Health and Welfare, 2014c). They are more likely to have shorter lives, increased risk factors and higher rates of chronic disease (Australian

Institute of Health and Welfare, 2014a) which, when combined with lower access to health care, is likely to contribute to poorer health outcomes (Australian Institute of Health and Welfare, 2014c). The rural context impacts on the capacity of health services to provide care.

In Australia there are twice as many rural hospital-based emergency facilities as there are metropolitan emergency departments (Baker & Dawson, 2014), but there are lower numbers of health professionals and most health services do not employ dedicated emergency department staff. Additionally, health service usage differs between rural and metropolitan locations due in part to limited access to general practitioner consultations and higher rates of admission to hospital (Australian Institute of Health and Welfare, 2013).

In response to the unique challenges for rural health services there has been a call for health reforms in service improvement by using new care models for the delivery of effective, appropriate and sustainable clinical care (Standing Council on Health of the Australian Health Ministers Conference, 2012b). A range of service and workforce models have been implemented, including the use of nurse practitioners, as a strategy to improve access, efficiency and quality of care for patients (Wilson et al., 2008).

The nurse practitioner service model is one of the most important developments in nursing in recent times, providing opportunity for significant reform in healthcare in Australia and internationally (Gardner, 2004). Currently, there are around 1,300 endorsed nurse practitioners in Australia working across a variety of specialty areas (Nursing and Midwifery Board of Australia, 2015), with emergency being the single largest specialty group (Middleton et al., 2011). The initial impetus for this service model was to improve access and equity of care for emergency department patients who were experiencing long waiting times, with excessive times for patient management, diagnosis and discharge (Maurice & Byrnes, 2001). The most common emergency department presentations affected by these service issues were those with minor illness and injury. Accordingly, these presentations were the early focus of emergency nurse practitioner service, especially in metropolitan settings.

Not-with-standing the challenges, the rural environment presents many opportunities for innovation. Emergency nurse practitioners are now utilised as a service model in 38% of rural emergency departments (Barnason & Morris, 2011) and nurse practitioners in these settings work to the full scope of their expanded role across all patient acuities including those presenting with undifferentiated chest pain.

Chest pain is a presentation of significance to emergency departments, representing 5-10% of all Australian annual patient presentations (George et al., 2013; Than et al., 2014). Chest pain is symptomatic of many aetiologies, one of which is acute coronary syndrome. This encompasses a broad spectrum of clinical presentations that includes acute myocardial infarction which is the leading cause of sudden death in the Australian population (Kinsman et al., 2012).

Whilst chest pain is a characteristic of acute coronary syndrome, the majority of patients with chest pain are ultimately found to have non-cardiac diagnoses (Cullen, Greenslade, Hammett., et al., 2013; George et al., 2013; Groarke et al., 2013; Meek et al., 2012). Not-with-standing the diagnostic outcome, there are considerable costs to health services in evaluating patients who are experiencing chest pain. In the context of increasing health service demand, the challenge for clinicians, including nurse practitioners, in caring for this patient cohort is balancing risk and resources to determine an appropriate pathway of care and emergency department disposition (Parsonage et al., 2013).

Despite increasing use of the nurse practitioner service model, there is a paucity of evidence that is reported in the national and international literature regarding the safety and quality of the service. Robust review of current literature reveals that no experimental or observational studies have been published that specifically focus on evaluation of the safety and effectiveness of the nurse practitioner service model in the rural context. Clearly then, in acknowledging the paucity of evidence, there is a requirement to evaluate the quality of health care for those patients presenting to rural emergency departments with a complex and significant health care complaint.

Methods

The aims of this study were to:

1. Examine the safety and quality of emergency nurse practitioner service in the provision of care in the rural emergency environment; and,
2. Evaluate the effectiveness of the emergency model in the management of patients presenting to emergency with undifferentiated chest pain.

Study design and setting

The **Ma**naging chest **P**ain in **R**ural **E**mergency **D**epartments (MaP-RED) study was a prospective multicentre longitudinal nested cohort design. The study population was recruited from three rural emergency departments in Queensland, Australia. The study sites had similar service capabilities, no specialist cardiac services and were all located more than 150km from the closest cardiac interventional hospital. All sites had both emergency nurse practitioners and medical officers providing management of patients presenting with undifferentiated chest pain.

Participants and Recruitment

Participants were enrolled consecutively between November 2014 and February 2016, at three rural emergency departments. Due to these logistical factors, enrolment did not start and finish at the same time at each site. Whilst multisite human research ethics committee approval was granted, individual site specific approvals were protracted leading to delays in commencement at individual sites. Criteria for inclusion included patients with atraumatic chest pain who were at least 18 years old and able to provide informed consent (or have a legally acceptable representative). Patients who met inclusion criteria were identified by the triage nurse or treating clinician and invited to participate in the study. Participants were recruited to the study at the occasion-of-service in the emergency department. All participants provided written informed consent. Using the diagnosis assigned by the treating clinician as determined at the time of emergency department discharge, a nested cohort was identified that consisted of patients with suspected or confirmed acute coronary syndrome. Specific diagnoses included, but were not limited to,

possible cardiac chest pain, angina pectoris, acute coronary syndrome and myocardial infarction.

Data collection and instruments

Data were collected at baseline and included demographic and clinical data. A self-administered patient questionnaire that measured patient-reported outcomes including satisfaction, quality-of-life and functional status was completed at baseline. Follow-up measurement occurred 30-days after the index presentation. Data were collected to examine for unplanned representation within seven-days of the occasion-of-service. This study was subsequently retrospectively registered with the Australian New Zealand Clinical Trials Registry, ACTRN12616000823471.

Variables

The independent variable was the clinician service model involved in management of the patient. For study purposes, the models were operationally defined as:

a) The emergency nurse practitioner service model included the delivery and coordination of care in the diagnosis, investigation, therapeutic treatment (including prescribing of medications and technical interventions) and referral for patients with undifferentiated chest pain, or

b) The standard care model was similar but delivered and coordinated by a medical officer.

The management for patients provided by the standard care model was similar but delivered and coordinated by a medical officer. In both models all clinicians worked collaboratively and within their scope of practice. Emergency department nursing staff assisted the clinicians in providing care to the patient. There was no allocation of intervention; rather the care delivery model followed the standard method of patient allocation. Patients were treated in order of clinical urgency, the next available clinician (emergency nurse practitioner or medical officer) provided care as per the Australasian Triage Scale (ATS) allocation. The ATS is an indicator of clinical urgency where a number corresponds to the recommended timeframe in which a patient should receive treatment; a score of "1" indicates those patients with

the most urgent needs through to a score of "5" representing patients with stable, minor symptoms or concerns (Australasian College of Emergency Medicine, 2002).

Dependent variables were:

(i) Adherence to evidence-based guidelines for the management of suspected or confirmed acute coronary syndrome,

(ii) Diagnostic accuracy of ECG interpretation,

(iii) Service indicators of waiting times, length-of-stay and did-not-wait rates,

(iv) Diagnostic accuracy as measured by unplanned representation rates,

(v) Satisfaction with care; and,

(vi) Quality-of-life and functional status.

These variables were studied and compared across the two clinician service model groups.

Data sources/measurement

Data relating to demographic and clinical indicators were collected prospectively by research assistants using a specifically designed data abstraction tool. Two tested and validated tools were used to develop a questionnaire that was completed by participants at the emergency department occasion-of-service. Follow-up questionnaires were posted to all study participants at 30-days after the initial emergency department presentation.

The first tool used was a modified Ausprac patient outcomes scale (Gardner et al., 2010) that incorporated multiple validated and tested tools. We used the components of satisfaction with care, that was derived from two sources (Allnut et al., 2010; Safran, 2002), coordination with care (Safran, 2002) and level of health service utilisation (Stanford Patient Education Research Centre, n.d.).

The second tool used was the SF-12® survey (QualityMetric, n.d.) to measure quality-of-life and functional status. The tool contains 12 items that are used to construct physical component summary (PCS) and the mental component summary (MCS) scores. The SF-12 has demonstrated reliability and validity (Snellman et al., 2012; Ware et al., 1996), including in Australia (Fisher, 1999; Sanderson & Andrews, 2002). The instrument has been used previously for investigation of

patients with non-cardiac chest pain (Cheung et al., 2009) and for patients managed by the ENP service in Australia (Dinh et al., 2012).

A self-administered questionnaire, using a component of the National Nurse Practitioner Survey (Gardner et al., 2010) was completed by the nurse practitioner in each participating emergency department at the commencement of the study. This tool is an instrument that was used in two previous national nurse practitioner censuses (Gardner, Gardner, Middleton, & Della, 2009; Middleton et al., 2011). The tool included items related to barriers and facilitators to practice and the professional (years of experience) and psychosocial (perceived level of competence) characteristics of the nurse practitioner. These data were collected to establish the structural characteristics of the emergency nurse practitioner service.

Statistical analysis

Sample size calculations were based on the primary outcome for the study and reported in the previously published study protocol (Roche, Gardner, & Lewis, 2015). Using the results from our preliminary study (Roche et al., 2014), we anticipated a six-month period for data collection; however, there were critical issues with participant recruitment necessitating termination of the study prior to achieving the requisite sample. Data analysis was performed according to the pre-published analysis plan (Roche et al., 2015).

Baseline characteristics were reported separately for each service model. Fisher's exact test was used to test for significant differences between groups for the dichotomous variables of sex, and regular general practitioner. The independent t-test was used to test for significant differences between groups for the continuous variables of age (mean and standard deviation) and number of emergency department attendance in the previous year (median and IQR). The remaining variables of interest were the categorical variables of Aboriginal or Torres Strait Islander status, employment status, Australasian Triage Score score, general practitioner service use, nurse practitioner service use and discharge diagnosis. Chi-square analysis was used to test for significant differences.

Descriptive statistics were used to present data for service indicators, unplanned representation within seven-days and to summarise the adherence to guidelines for patients within the nested cohort. A blinded assessor who has

specialist qualifications in emergency medicine performed independent interpretation of ECGs, which was compared to the clinician's interpretation. Dichotomous data were displayed as a percentage of agreement proportion; comparisons between the service models were examined and tested for significance using Fisher's exact test. Dichotomous data for unplanned representations were presented as an odds-ratio. Data were compared between service models and tested for significance using the Mann Whitney U test for analysis of service indicators and Fisher's exact test for analysis of unplanned representations.

We used the Chi-square test and, where appropriate Fisher's exact test, to compare data for patient satisfaction between service models. In the quality-of-life and functional status assessment, data for the SF-12® summary scores were managed according to the Developer's guidelines. Data were presented using mean (SD) and were tested for significance using paired t-test. Regression analysis was conducted to evaluate the association between service model and quality-of-life and functional status, adjusted for age and gender. Using the results of this regression, the predicted means for the summary scores at the occasion-of-service and for the follow-up examination for each service model were calculated using the study cohort mean age. These data were compared for each service model and compared for statistical significance using the independent samples t-test.

All statistical analyses were conducted using de-identified patient data using SPSS (Version 24). The significance level was set at $p<0.05$.

Results

A total of 61 participants were recruited to the study from the three participating sites. Of these 23 (37.7%) participants were managed using the emergency nurse practitioner service model, whilst the remaining 38 (63.3%) were managed using the standard care model (see Figure 11). Differing levels of experience for the medical officers leading the standard care service were observed, however, the majority of participants (n=28, 73.7%) managed by this service model were reviewed by a senior medical officer (see Figure 11).

Baseline characteristics

Analysis of baseline participant characteristics found no significant difference between the two groups. The age of participants ranged from 20.8 years to 95.7

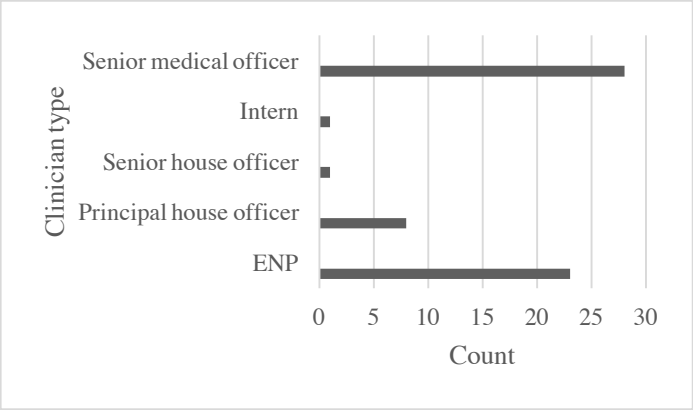

Figure 11 Participant numbers by clinician type

years. The mean age of participants was 61.0 years (SD 15.5) and 57.4% of the study cohort were female. There were few Aboriginal or Torres Strait Islander participants (n=5, 8.2%). Retired or aged pensioners accounted for more than half (54.1%) of the study cohort. The majority of the participants had completed high school or had higher educational qualifications (62.4%). The majority of participants were allocated either Australasian Triage Score 2 or Australasian Triage Score 3 (92.6%). The vast majority of participants had not previously used a nurse practitioner service (80.3%), reported having a regular general practitioner (91.5%) and attended their general practitioner "every couple of months" (44.3%). The median number of emergency department attendances in the previous year was one (IQR 3). There were no differences in the baseline characteristics for either service model. Table 11 provides a summary of all patient characteristics.

Notably cardiac conditions were implicated in the majority of participants recruited to the study (79.3% of all diagnoses for participants recruited to the study), followed by non-cardiac chest pain (n=4, 7.4%). The remainder of diagnoses included participants with psychiatric, infectious, gastrointestinal and musculoskeletal conditions (see Figure 12). The single most common discharge diagnosis was "possible cardiac chest pain", which represented 63.0% (n=34) of all presentations for participants recruited to the study.

Table 11 Baseline patient characteristics

	Standard care n=38	ENP service n=23	p value
Sex			
Male	19	7	
Female	19	16	0.18
Age - years			
Mean (SD)	61.7 (15.4)	59.9 (16.0)	0.66
Aboriginal or Torres Strait Islander status (n=52)			
Not ATSI	25	22	
Aboriginal not TSI	3	1	
TSI not aboriginal	1	0	0.47
Employment status (n=60)			
Employed	11	8	
Pensioner	21	12	
Unemployed	2	0	
Student	1	0	
Home duties	1	2	
Other	1	1	0.67
Highest level of education (n = 57)			
Primary school only	16	6	
High school	11	5	
Higher qualifications	9	10	0.21
Australasian Triage Score category (n = 54)			
ATS 2	21	5	
ATS 3	13	11	
ATS 4	2	2	0.10
Regular general practitioner (n = 59)			
Yes	35	19	
No	2	3	0.35
Emergency department attendances in the past year (n=60)			
Median (IQR)	2 (4)	1 (2)	0.26
General practitioner service use in past year (n=56)			
Not at all	0	1	
Once or twice	13	3	
Every couple of months	14	13	
Once a month	2	2	
More regularly	5	3	0.28
Nurse practitioner service use in past year (n=58)			
Not at all	30	19	
Once or twice	4	3	
Once a month	2	0	0.72

The majority of participants were admitted to the health service at the completion of the emergency department occasion-of-service (77.8%, n=42), nine participants were discharged (16.7%) and the remaining three (5.6%) were transferred to another hospital directly from the emergency. Of the participants admitted to hospital, the majority 63% (n=34) were admitted to the high dependency / short stay unit (HDU / SSU) and the remainder were admitted to the medical unit (14.8%, n=8).

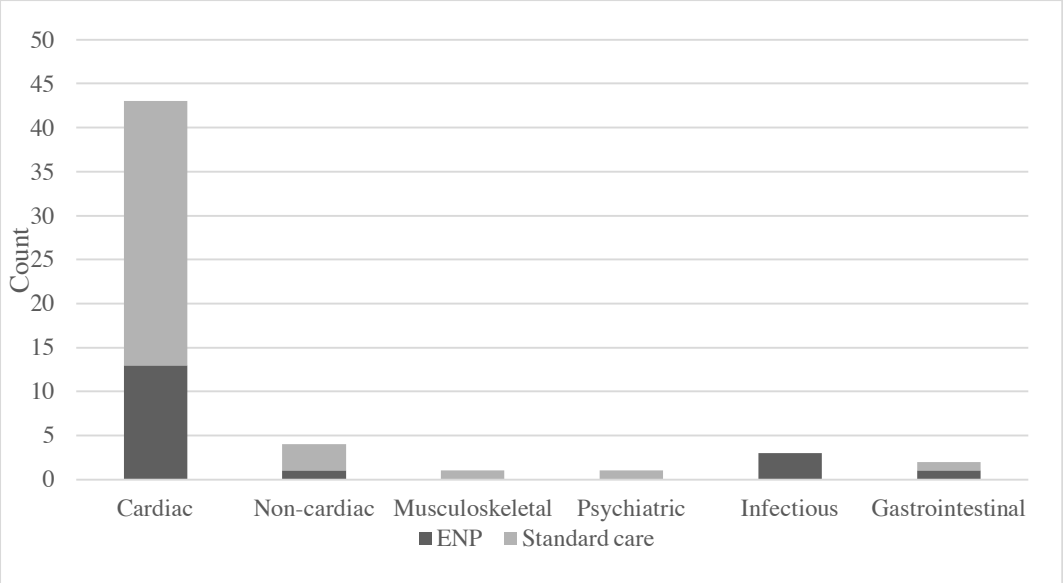

Figure 12 Diagnosis on discharge by condition for each service model

Adherence to guidelines – Primary outcome

Forty-one participants were identified for inclusion in the nested cohort. The proportion of agreement by service model is presented in Table 12. Although it appeared that the standard care model achieved a higher proportion of adherence to recommendation for timely electrocardiograph review, there was no statistical difference between groups (Fisher's exact test = 0.11).

Table 12 Adherence to guidelines for the nested cohort (suspected or confirmed acute coronary syndrome) by service model - proportion of agreement

	Standard care n=28	ENP service n=13	p value
Oxygen, aspirin and pain relief ordered			
Oxygen administered only to patients with hypoxia (SaO_2 <93%) (n=40)			
Compliant	82.1%	100%	
Non-compliant	17.9%	0%	0.20
Aspirin prescribed in ED (n=41)			
Compliant	89.3%	100%	
Non-compliant	10.7%	0%	0.31
12 lead ECG performed and reviewed within 10 minutes of presentation (n=36)			
Compliant	73.9%	53.8%	
Non-compliant	26.1%	46.2%	0.11
Troponin testing on arrival to ED (n=41)			
Compliant	92.9%	100%	
Non-compliant	7.1%	0%	0.46
Chest x-ray scheduled (n=41)			
Compliant	60.7%	61.5%	
Non-compliant	39.3%	38.5%	0.62
Repeat troponin testing at 6-8 hours (n=40)			
Compliant	82.1%	91.7%	
Non-compliant	17.9%	8.3%	0.25
NSTEACS and high-risk patient management			
Clopidogrel administered in ED (n=20)			
Compliant	64.3%	83.3%	
Non-compliant	35.7%	17.7%	0.17
Enoxaparin administered in ED (n=19)			
Compliant	71.4%	80.0%	
Non-compliant	28.6%	20.0%	0.51
STEMI management (n=2)			
Thrombolysis given if not contraindicated			
Compliant	100%	100%	
Non-compliant	0%	0%	

Diagnostic accuracy of electrocardiograph interpretation

The emergency nurse practitioner model achieved a higher proportion of agreement (91.7%) than the standard care model (82.8%) for diagnostic accuracy of electrocardiograph interpretation (Fisher's exact test = 0.52) (see Figure 13).

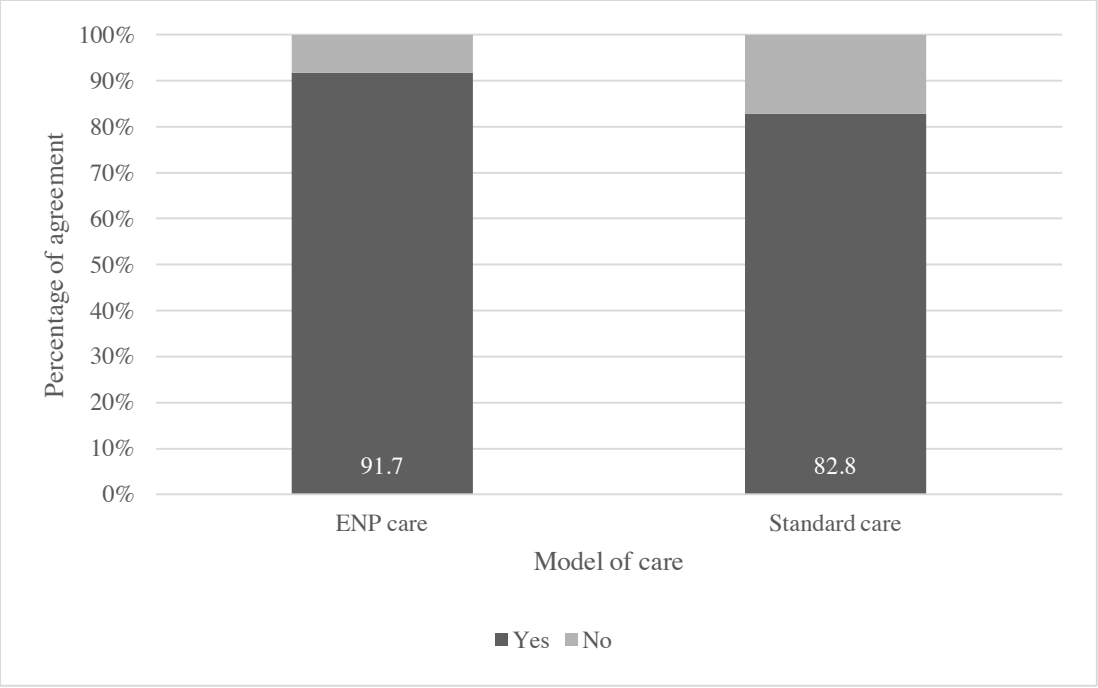

Figure 13 Diagnostic accuracy of ECG interpretation - percentage of agreement by service model

Service indicators

For the study cohort, the minimum waiting time was 0 minutes, whilst the maximum waiting time was 60 minutes. The mean waiting time was 13.2 minutes (SD 15.2) and the median waiting time was 8.0 minutes (IQR 20). Data was not normally distributed (skewness = 1.24, kurtosis = 0.74). The minimum LOS was 23 minutes, whilst the maximum LOS was 375 minutes. The mean LOS was 116.0 minutes (SD 71.6) and the median LOS was 100.0 minutes (IQR 64). Data were not normally distributed (skewness = 2.12, kurtosis = 5.12). For this study, there was no incidence of participants not waiting to be seen by the care models (Did-not-wait rate = 0%). Table 13 provides a summary of service outcome indicators comparison by service model.

Table 13 Service outcome indicators comparison by service model

Outcome	Standard care *Median (IQR)*	ENP model *Median (IQR)*	Difference *Minutes*	p-value
Waiting time minutes	7.5 (20)	8 (23)	0.5	0.4
Length of stay minutes	101.5 (54)	97.0 (91)	4.5	0.8

Diagnostic accuracy as measured by unplanned representation within seven-days

Four participants had an unplanned representation within seven-days. All participants who had an unplanned representation were managed in the standard care model. Participants were 2.4 times more likely to have an unplanned representation if managed by the standard service model (Fisher's exact test, p=0.29).

Satisfaction with care

At the occasion-of-service all participants were satisfied with the care; 91.5% of participants reported being "highly satisfied" and 8.5% of participants were "satisfied". There were no differences found between service models (Fisher's exact test = 0.96).

A high level of rapport between clinicians and participants was demonstrated for both baseline and follow-up measures. All participants reported that they were able to talk easily and openly and the clinician answered all questions and concerns. There were differences found between service models for the remaining areas of investigation (see Table 14).

At follow-up, there was little change in the levels of participant satisfaction with care, with 93.2% "highly satisfied" and the remaining 6.8% responding that they were "satisfied" with the care they received in the emergency department. There were no differences found between service models (Fisher's exact test = 0.98). All participants reported that they would be "very happy" to reattend the emergency department with chest pain if needed.

Table 14 Satisfaction with care - differences between service models

	Standard care model	ENP care model	p value
How often did the clinician explain things to you in a way that was easy to understand? (n=60)			
Always	81.1%	78.3%	
Almost always	16.2%	21.7%	
Usually	2.7%		0.65
How often did the clinician listen carefully to you? (n=60)			
Always	86.5%	95.7%	
Almost always	13.5%	4.3%	0.25
Did you feel that the clinician spent enough time with you? (n=58)			
Yes, definitely	97.3%	100%	
Yes, somewhat	2.7%		0.44
Did the clinician tell you in detail about the risks and side effects of the recommended treatment? (n=33)			
Yes, definitely	75.9%	78.6%	
Yes, somewhat	20.7%	14.3%	
No, definitely not	3.4%	7.1%	0.78
Did the clinician give you enough information about treatment choices? (n=24)			
Yes, definitely	90.0%	75.0%	
Yes, somewhat	10.0%	25.0%	0.30
Did the clinician ask which treatment you preferred? (n=21)			
Yes, definitely	78.9%	66.7%	
Yes, somewhat	21.1%	22.2%	
No, definitely not		11.1%	0.33
Did the clinician assist you to make changes in your lifestyle to improve your health or prevent illness? (n=56)			
Yes, definitely	29.3%	13.3%	
Yes, somewhat	12.2%	26.7%	
No, definitely not	2.4%	0%	
No help required	56.1%	60.0%	0.35

Quality-of-life and functional status

The mean PCS score for the study cohort did not change significantly ($t_{(41)}$ = 0.51, p=0.96) between the occasion-of-service (44.90, SD 11.6) and follow-up (44.86, SD 11.8). Participants had a change in mean MCS score between the occasion-of-service (47.76, SD 10.7) and follow-up (49.23, SD 10.5), a statistically significant increase of 1.47 (95% CI 0.05 to 3.0), $t_{(41)}$ = 1.96, p=0.05 (see Figure 14). When adjusted for age and sex, there was no difference between predicted PCS and MCS scores between service models (see Table 15).

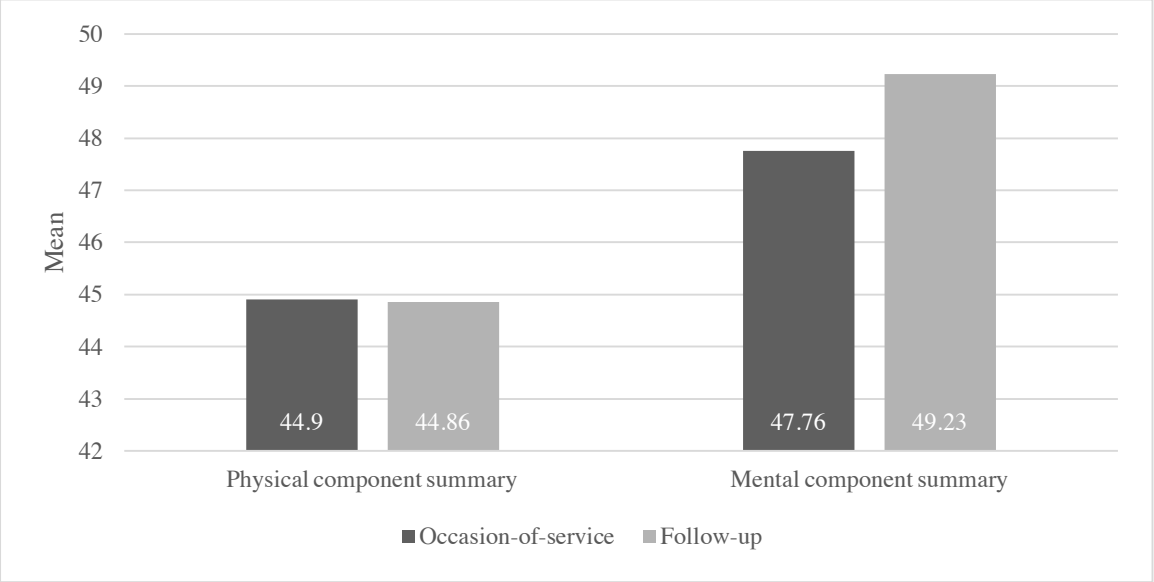

Figure 14 Summary scores for components of SF-12 survey

Table 15 Comparison of predicted means summary scores for SF-12 – adjusted for age and sex

	Standard care Predicted mean	ENP service Predicted mean	p value
Physical Component Summary			
Occasion-of-service	44.39	47.49	0.11
Follow-up	44.07	46.98	0.17
Mental Component Summary			
Occasion-of-service	49.58	48.63	0.59
Follow-up	49.16	48.14	0.62

Discussion

This study lends support to the evidence of effectiveness of the emergency nurse practitioner service model when compared to the standard care model in the

provision of care to rural patients with complex health care needs. Although problems with patient recruitment ultimately led to an underpowered study, due to the paucity of research in this field it is important that these study results are available for potential subsequent meta-analysis in reviews or studies evaluating the effectiveness of the emergency nurse practitioner service model.

Adherence to guidelines

Clinical guidelines have the fundamental goal of improving the quality and safety of health care by ensuring evidence based practice and reducing variations in health care (Thomas et al., 1999). Despite this, there are often gaps between the guideline recommendations and clinical practice, that may result in patients not receiving appropriate care (Grol et al., 2003; van Achterberg, Schoonhoven, & Grol, 2008). Few studies have examined the extent of adherence to clinical guidelines in the emergency environment (Ebben et al., 2013). Consequently, little is known about guideline use in the Australian context and in particular in the rural setting. Previous evaluation has found 38% adherence to guidelines for the management of adult patients presenting to an Australian metropolitan emergency department with asthma (Doherty, Jones, Davis, Ryan, & Treeve, 2007). The National Heart Foundation and Cardiac Society of Australia and New Zealand guidelines (Chew et al., 2011; "Management of unstable angina. Guidelines--2000. The National Heart Foundation of Australia, The Cardiac Society of Australia and New Zealand.," 2000) provide recommendations on the risk stratification and management of patients presenting to EDs with suspected or confirmed acute coronary syndrome. This is the first study to examine the extent to which these guidelines are followed for the cohort of patients presenting to rural EDs with chest pain. Overall, adherence to the guidelines by clinicians in this study was good with clinicians achieving a minimum of 64% compliance with acute coronary syndrome guidelines.

Oxygen appeared to be overused by the standard care model. The guidelines recommend oxygen be administered to those with hypoxia (SpO_2 less than 94%) or signs of shock. For this study, non-compliance occurred when oxygen was administered when not clinically indicated. A recent systematic review (Cabello, Burls, Emparanza, Bayliss, & Quinn, 2013) found no conclusive evidence to support the routine use of supplemental oxygen and suggested that there may be an increased risk of death to patients with acute coronary syndrome who received oxygen.

A high proportion of participants (greater than 82%) were administered aspirin in our study. This compares well with a 2007 cross-sectional study of 544 emergency departments in the USA that aimed to evaluate the proportion of patients receiving guideline recommended care in acute coronary syndrome and found that aspirin was administered to only 40% of patients in the study (Pham, Kelen, & Pronovost, 2007).

In the same way, a high proportion of participants in our study (greater than 82%) had cardiac biomarker testing performed on arrival to emergency department and repeated at the guideline recommended interval. On the other hand, there was suboptimal adherence to 12-lead electrocardiograph review within 10 minutes of presentation (53%) and chest x-ray scheduling (60.7%). Although two-thirds of ECGs performed were in accordance with guidelines, there was an inappropriately high proportion of patients that did not have timely review of their electrocardiograph. It is possible that non-adherence to guideline with regard to chest x-ray scheduling may have occurred because of barriers specific to the rural environment. For the participating sites in this study radiology services are on-call after hours, which may have led to clinicians appropriately rationing resources and not performing routine x-ray investigations on clinically well patients.

Our results show that there was a higher proportion of guideline adherence for high-risk patients and those with diagnosed acute coronary syndrome by the emergency nurse practitioner service model. The guideline adherence rate was greater than 80% for administration of both clopidogrel and enoxaparin, whilst the standard care model achieved 64.3% and 71.4% respectively. Furthermore, although the standard care model achieved a good level of adherence to the guidelines, the proportion of patients receiving guideline-recommended care was lower than that achieved by the emergency nurse practitioner service model. The reason for this may be that the medical officers studied may have preferred to exercise professional autonomy in making clinical judgements based on personal experience, which has been found to influence adherence to emergency department guidelines (Ebben, Vloet, de Groot, & van Achterberg, 2012).

Diagnostic accuracy of electrocardiograph interpretation

Whilst research has found that emergency nurse practitioner service achieves high diagnostic accuracy, previous investigations have been primarily conducted in the area of minor injury and illness with studies reporting on missed injury and fracture rates (Lau et al., 2013; Thompson & Meskell, 2012; van der Linden et al., 2010). This study is the first to evaluate the diagnostic accuracy of emergency nurse practitioner service in complex investigation. This care model achieved a higher level of diagnostic accuracy of electrocardiograph interpretation (91.7%) than the standard care model (82.8%). Whilst there is no single or combination of clinical features that can be used to exclude acute coronary syndrome, the initial evaluation and management of a patient with undifferentiated chest pain requires a meticulous clinical assessment with interpretation of electrocardiograph being the cornerstone of the assessment (Parsonage et al., 2013). A missed diagnosis of acute coronary syndrome may result in a delay in initiating the appropriate treatment and increasing the mortality rate (Pope et al., 2000; Schull et al., 2006). In the context of the findings of this study, there was the potential for nearly one-fifth of all patients presenting with undifferentiated chest pain to be exposed to significant risk from either a missed opportunity for intervention or from further unnecessary testing and intervention.

Service indicators

This study found no significant difference between the two clinician groups with regard to waiting times, length-of-stay and did-not-wait times. This finding is consistent with the most recent research that has evaluated emergency nurse practitioner service on these indicators in Australian emergency departments (Jennings, Gardner, et al., 2015b). Although other studies have demonstrated a reduction in the length-of-stay for patients managed by an emergency nurse practitioner service (Colligan et al., 2011; Considine et al., 2010), these findings are limited because there was no standardised definition for the clinician groups studied. In these studies (Colligan et al., 2011; Considine et al., 2010), doctors with lower levels of experience required "sign-off" by a senior colleague and there were marked differences in the responsibilities of these clinicians whilst the emergency nurse practitioner comparator had lower levels of interruption with a clear focus on the management of minor injury and illness. Furthermore, many of these studies were

based on retrospective audit data rather than prospective studies (Ducharme et al., 2009; Jennings et al., 2008, 2013). Our prospective cohort study avoided these limitations and the majority of patients that were managed in the standard care model had a senior medical officer as the lead clinician.

Diagnostic accuracy as measured by unplanned representation within seven-days

The overall unplanned representation rate for patients presenting to rural hospitals with undifferentiated chest pain was 6.6%, higher than the 0.6% rate previously reported (Roche et al., 2014). In our study patients were more than twice as likely to have an unplanned representation within seven-days if they were managed in the standard care model. Of these half represented with chest pain. Whilst studies have demonstrated no difference between clinician groups (Colligan et al., 2011; Dinh et al., 2012) in unplanned representation rates other studies support our findings (Feetham et al., 2015; Nash et al., 2007). As previously indicated, the majority of patients who present to emergency department with undifferentiated chest pain will have no cardiac cause and will be ultimately discharged with a diagnosis of non-cardiac chest pain. This patient cohort has been found to have increased anxiety, reduced quality-of-life, further chest pain and an increased demand for health care services (Eslick, Coulshed, & Talley, 2002; Goodacre, Mason, Arnold, & Angelini, 2001; Webster, Norman, Goodacre, Thompson, & Mceachan, 2014).

Satisfaction with care

The acceptability of the emergency nurse practitioner service has been clearly established with consistently high levels of patient satisfaction reported in the literature (Dinh et al., 2013; Jeanmonod et al., 2013; Jennings et al., 2009; Lutze et al., 2013; McDevitt & Melby, 2015; Sandhu et al., 2009; Thrasher & Purc-Stephenson, 2008; Wilson et al., 2009). Our study supports this evidence in finding the majority (88.5%) of participants were highly satisfied with the overall quality of care, which was sustained over time. At the follow-up evaluation, 93.2% of participants reported that they were highly satisfied with the overall quality of care. Whilst previous studies (Dinh et al., 2013; Dinh et al., 2012; Jennings et al., 2009; Lutze et al., 2013) have found higher levels of patient satisfaction with emergency

nurse practitioner service when compared to the standard care model, our study did not demonstrate any significant difference between models.

The entirety of participants from both groups reported that the clinician seemed informed and up-to-date and the majority reported that the clinician assisted them to make lifestyle changes to improve their health. Pursuing this further, participants in our study had a high level of rapport with clinicians. The majority reported that they could discuss their concerns and be listened to carefully, explanations by the clinician were easily understood and participants felt involved in their health care decision making. In the same way Jeanmonod, et al. (2013) also found that the majority of patients of an emergency nurse practitioner service felt cared about, were kept aware of tests and had their problems and follow-up explained. In addition, our study found that high levels of satisfaction with care were maintained at follow-up evaluation.

Quality-of-life and functional status

Participants in our study were found to have change in the MCS summary score at follow-up measurement (+1.47). Whilst statistically significant (p=0.05), this is not clinically relevant and unlikely to represent an improvement as a result of service intervention. There were no differences between participants from either service model.

The mean PCS and MCS score when adjusted for age and sex for Australian adults with heart disease had previously been recorded as 44.4 and 50.2 respectively (Avery, Grande, & Taylor, 2004). Similarly, a mean PCS of 40.90 (SD 11.7) and MCS of 49.14 (SD 10.9) has been reported for patients with ACS (Melville, Lari, Brown, Young, & Gray, 2003). The mean summary scores for the SF-12 for our study cohort were comparable to these findings.

Strengths and limitations of the study

This was an observational study. Although a randomised controlled trial would have met the "gold standard" for research, in this case it was not feasible to implement emergency nurse practitioner clinicians as a service intervention. The service was already established and hence an observational study was conducted consistent with established practice to evaluate the quality of patient and service outcomes.

The major limitation of our study is the small sample size that has led to an inability to compare the safety and quality of care for the service models with statistical significance. Whilst initial estimates of presentations in the participating hospital indicated sufficient numbers for our sample size estimates, requisite patient recruitment did not proceed as anticipated. The issues with patient recruitment may have also introduced selection bias; despite a standardised protocol patient recruitment varied across sites.

Our study benefits from rigorous research methods and the use of an appropriate study design. We used a suite of validated and well tested tools to evaluate the multiple dimensions of the emergency nurse practitioner role, including the substance of nursing care and its influence on patient outcomes. In assessing the diagnostic accuracy of electrocardiograph interpretation we used an emergency consultant (the "gold standard") for blinded assessment of electrocardiographs. The study design avoided the limitations of previous emergency nurse practitioner research by using qualified emergency nurse practitioners working to the full scope of their role and a standardised comparator.

Conclusion

The MaP-RED study is the first reported study that has examined the effectiveness of emergency nurse practitioner service in the management of patients presenting to rural EDs with chest pain. Our study found a high level of adherence to clinical guidelines for the emergency nurse practitioner service model and a concomitant high level of diagnostic accuracy. In the area of evaluation of the service indicators of waiting time and length-of-stay the emergency nurse practitioner service demonstrated comparable effectiveness to that of the standard care model. In addition, excellent patient reported outcomes for the emergency nurse practitioner service model were demonstrated.

These findings provide a foundation for the beginning evaluation of rural emergency nurse practitioner service in the delivery of safe and effective care beyond the minor illness and injury cohort.

List of abbreviations

ACS: Acute coronary syndrome **ED:** Emergency department

ENP: Emergency nurse practitioner **NP:** Nurse practitioner

Declarations

Ethics approval and consent to participate

The study was approved by the Queensland Health Human Research Ethics Committees (Approval numbers HREC/14/QHC/030 and HREC/15/QTDD/18) and the Queensland University of Technology Human Research Ethics Committee (Approval number 14500000709).

Consent for publication: Not applicable

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Competing interests

None declared.

Funding

TR was funded by an Australian Postgraduate Awards scholarship through Queensland University of Technology. The scholarship has enabled her to undertake doctoral studies in which this project was conducted.

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Author contributions

TR conceived and designed the study with GG. TR and GG participated in designing and developing the study instruments and procedures. TR analysed the data under the guidance of GG. TR, GG and LJ contributed to the interpretation of results. TR wrote the manuscript, and GG and LJ revised it critically for important intellectual content. All authors approved the final manuscript.

Acknowledgements

The authors would like to acknowledge the cooperation of the rural health services for participating in this study. We appreciate the nurses and medical students who gave their valuable time to act as research assistants.

END OF SUBMITTED MANUSCRIPT

References for the submitted manuscript are included in the thesis reference list

5.2 STRUCTURAL CHARACTERISTICS OF THE EMERGENCY NURSE PRACTITIONER SERVICE MODEL

The submitted manuscript reported the results from the evaluation of the primary outcome variable, adherence to guidelines, and the secondary outcomes of service indicators and patient reported outcomes. However due to the word limitation requirements of publishing, data on the extraneous variable, structural characteristics of the ENP service model, was not reported. Chapter 4 provided introduction and presented the rationale for use of the Donabedian Structure-Process-Outcome framework for this evaluation of the ENP service model. Accordingly, this section of the Chapter will report the results of the examination of the structural characteristics of the ENP service model.

The study design and setting have been previously described in the previous Chapter. To summarise, each ENP from the three study sites were invited to participate in the study. At the commencement of research for each site, informed consent was obtained from ENP participants for inclusion in the study. Data were collected using a self-administered questionnaire that comprised both demographic data and a component of the National Nurse Practitioner Survey (Gardner et al., 2010). These data were collected to determine the structural characteristics of the ENP service.

To achieve this goal, the following outcomes were assessed: (i) professional characteristics; (ii) barriers and facilitators for ENP practice; and, (iii) psychosocial characteristics. Descriptive statistics were used to present data for these outcomes. Due to the ENP participant small sample size, results were presented as counts in narrative as they relate to the Donabedian Structure dimension.

5.2.1 Results

A total of four ENP participants were recruited to the study from the three participating sites. No nurse practitioner from any site declined to participate in this research.

Professional characteristics (years of experience)

The age of participants ranged between 32 and 39 years. The mean age of ENP participants was 40.5 years (SD 6.95). These ENPs were experienced clinicians, with the mean length of experience as a registered nurse being 15.7 years (SD 4.11).

The minimum years of experience was 11 years and the maximum was 21 years. There was considerable variance in the amount of experience as an endorsed NP between participants; ranging from 14 to 62 months. The median months of employment as a NP was 21 months (IQR 38).

Barriers and facilitators for ENP practice

The questionnaire used a series of seven items to assess the barriers and facilitators for ENP practice. Each item had six possible responses ranging from 1 not at all limiting – 5 extremely limiting. The following items were assessed: (i) lack of Medicare provider number; (ii) support from within the nursing profession; (iii) support from medical colleagues within the health service; (iv) support from colleagues receiving ENP referral; (v) organisational support; and, (vi) legislative support.

Data reporting the lack of a Medicare provider number was clearly split between the two extremes for this item; two ENPs reported a lack of Medicare provider number extremely limiting, whilst the other two participants reported this as not at all limiting. Both ENPs reporting this item as extremely limiting were employed at the same study site.

In the evaluation of support for the ENP service model there was a range of responses for each item. The majority of ENPs (n=3) were ambivalent regarding support from within nursing scoring this item a "3" (neither not at all limiting or extremely limiting). The final ENP, who had the greatest length of ENP experience, scored this item a "2". Similar, for the item "support from medical colleagues" two of the participating ENPs scored this item "3". Interestingly, the final two ENP responses for this item were very dissimilar (a score of "2" and "5") in the circumstance of both ENPs being employed at the same study site. Two ENPs reported the service experienced few limitations when referring to colleagues (scoring a "2"), another ENP was ambivalent ("3") and the remaining ENP reported extremely limited support. For the two ENPs employed at the same study site, organisational support was not limiting or facilitating (scoring a "3") to the service model. The remaining two ENPs reported extremely limited organisation support (scoring a "5") for the service model. Lastly, notwithstanding all participating ENPs being employed under the same legislative conditions, there was limited agreement between the ENPs in the evaluation of legislative support for the model. There was

also no significant evidence toward either the existence or lack of legislative support; two scores of "3", one of each "2" and "4" were provided.

Psychosocial characteristics (perceived level of competence)

The highest score for this item was a "2" (indicating a high level of perceived competence) was reported by a single ENP, who also possessed the greatest level of experience as a NP. The remaining ENPs (n=3) were ambivalent about their self-reported competence.

5.3 SUMMARY

This Chapter presented the results of the **Ma**naging chest **P**ain in **R**ural **E**mergency **D**epartments study, a prospective longitudinal nested cohort study that investigated the safety and quality of the ENP service in the management of patients presenting to rural emergency departments with a complex health care condition. This research serves as the first enquiry into the effectiveness of this service level in both the rural setting and for the cohort of patients presenting with undifferentiated chest pain that were included in this study. The study used validated tools in the assessment of multiple outcomes including the structure, processes and outcomes of care. The MaP-RED study has evidenced a higher proportion of guideline adherence for high-risk patients and those with diagnosed acute coronary syndrome who were managed by the emergency nurse practitioner service model. Overall, adherence to the guidelines by clinicians in this study was good with clinicians achieving a minimum of 64% compliance with acute coronary syndrome guidelines. The emergency nurse practitioner model achieved a higher proportion of agreement (91.7%) than the standard care model (82.8%) for diagnostic accuracy of electrocardiograph interpretation (Fisher's exact test = 0.52). There were no significant differences between the two groups in regards to the service indicators of waiting time and length-of-stay. Participants were 2.4 times more likely to have an unplanned representation within seven-days if managed by the standard service model (Fisher's exact test, p=0.289). No differences between the service models was found for patient-reported outcomes. The majority (88.5%) of participants were highly satisfied with the overall quality of care, which was sustained over time. At the follow-up evaluation, 93.2% of participants reported that they were highly satisfied with the overall quality of care. The mean summary scores for the SF-12

for our study cohort were comparable with contemporary research. These findings provide a foundation for the beginning evaluation of rural emergency nurse practitioner service in the delivery of safe and effective care beyond the minor and illness setting.

Chapter 6: Discussion

6.1 INTRODUCTION

The overall aim of the study was to examine the effectiveness of the rural ENP service model. Specific aims were to:

i) Examine the safety and quality of the ENP service model in the provision of care in the rural environment, and

ii) Evaluate the effectiveness of ENP service in the management of patients presenting with undifferentiated chest pain.

The Donabedian Structure-Process-Outcome Model described in Chapter 4 was ascertained as being suited to this evaluation. Based on Donabedian's framework, it may be concluded that robust health services structures will influence the establishment of evidence-based processes will in turn create better outcomes for patients presenting to rural EDs with chest pain. For this research, the health service structures influencing the ENP service model, the processes and outcomes for patients presenting to rural EDs with chest pain were examined to contribute new knowledge to this reform model. The timing and value of this research are highly relevant in the current health care context and the research seized the opportunity to study ENP service. The research was unique in that this was the first study, to our knowledge, to examine rural ENP service outside the minor injury and illness context. Despite the increasing use of ENPs in rural areas, there was a paucity of evidence that has been reported in the literature. No other experimental or observational studies in this context have been undertaken previously. Additionally, this research brings attention to the work of NPs in the emergency setting that draws upon knowledge and skills applied to care of patients at the high end of the acuity spectrum. This level of practice has not previously been systematically reported or examined.

The preliminary study (see Chapter 3) demonstrated that chest pain was a presentation of significance for rural health services. Of all ED presentations to rural hospitals, chest pain complaints accounted for 3.5% of total presentations. Further more than 40% of these patients require admission to hospital, with the majority of

these admissions being necessitated by a risk stratification strategy that dictates a high proportion of patients be admitted for further investigation and management. The current recommended approach for the management of patients presenting with chest pain (the CSANZ/HFA guidelines) pose significant costs to rural health services with limited access to functional testing and invasive treatments. The systematic review (Chapter 2) identified a risk stratification tool that was safe and effective for use in the cohort of patients presenting to rural hospitals with chest pain. The prospective nested cohort study described for the first time the structural characteristics of the rural ENP service finding a younger, less experienced cohort of practitioners who reported no specific barriers or facilitators for their practice. For the processes and outcomes of care for rural patients with chest pain, no differences between ENP service and standard medical care were demonstrated.

Although this study was underpowered to confirm the study hypotheses, the results were significant. Data from underpowered studies that use methodological rigor to eliminate bias and are accurately reported should be made routinely available (Cleophas & Cleophas, 1999; Lilford & Stevens, 2002; Schulz & Grimes, 2005). Furthermore, in this case these results play an important role as foundation evidence for the evaluation of the ENP service in a previously unknown context, with an unbiased study with imprecise results far better than no results at all (Schulz & Grimes, 2005). For these reasons, a publication presenting the study results was considered to be important notably for the purpose of future research, given the paucity of research in this field that was identified in Chapter 2.

This Chapter presents a detailed discussion on the results of the research that was conducted for this service evaluation. The literature review identified the need for a research design that could take into account the complexity of the multiple dimensions, especially in with regard to the background and context of the rural ENP service (see Chapter 1). The following sections present discussion of the results of this research according to each dimension of the Donabedian framework that was used to inform and organise the research process. The Chapter concludes with a discussion of the strengths and limitations of this research and includes a manuscript reporting the issues for rural health services outcomes research that has been submitted to *Australian Health Review*.

6.2 STRUCTURE DIMENSION

As previously described, according to the Donabedian framework, *Structure* refers to the attributes of the health care setting (Donabedian, 1988), specifically relating to the fundamental elements required for an effective service model. For this research, the dimension of structure was used to evaluate the professional and psychosocial characteristics of the ENP service model, as well as the barriers and facilitators for practice.

The study demonstrates that the rural ENPs in our cohort are considerably younger and less experienced as registered nurses than those studied in the last national census of Australian NPs (Middleton et al., 2011). The mean age of ENPs in our study was 40.5 years and the length of time employed as a registered nurse was 15.7 years. The rural context itself most likely provides explanation for this finding, by providing opportunity for early career development for its nurses. Faced with crucial medical workforce issues (Humphreys, Jones, Jones, & Mara, 2002) and rural hospitals struggling to maintain health services (Kenny & Duckett, 2003), nurses have played a vital role in the delivery of services. The existing rural health service culture has a reliance on rural nurses to be multi-skilled generalists with a wide range of advanced skills (Hegney, 1997), often making clinical decisions in the absence of other health professionals (Hegney & McCarthy, 2000). In Australia, registered nurses who seek endorsement as NPs are required to complete a Master's degree. Students applying to these courses must demonstrate a minimum of three years of experience working at an advanced practice level. The development and utilisation of ENP models of care in rural health service represents a natural progression for these career rural nurses.

No specific rural health service structural characteristics were reported the ENP cohort as being barriers or facilitators to the service model. Results from the two national nurse practitioner censuses (Gardner et al., 2009; Middleton et al., 2011) concluded that the majority of Australian NPs reported significant barriers to practice, with concerns about the capacity to care for patients to the full extent of the NP role noted (Gardner et al., 2009). Other research, more specific to the rural context of ENP practice, demonstrated that a lack of support from the organisation and colleagues was a barrier to senior nurses considering NP endorsement (Ling, Curtis, Brighton, & Dunlop, 2013). These concerns were not supported by the

results of our study. Not-with-standing the challenges, the rural environment presents many opportunities for innovation, including the use of ENP service. The ENPs surveyed did not express concerns regarding a lack of support from nursing or medical colleagues, legislation or organisational support.

Evaluating self-perceived competence provides an indication of the individual's motivation in maintaining and improving skills (Lai & Cheong, 2011) and is a component of self-efficacy, one's belief in their ability to succeed in specific situations or accomplish a task. Despite the rural setting providing preparation for extensions to nursing practice, the ENPs in our study do not perceive themselves as either being limited or not limited by their self-perceived role competence. This finding was concerning; previous knowledge has suggested that a professionals' self-efficacy plays an important role in overall job performance (Judge & Bono, 2001) and further, in the case of low self-efficacy, practice could fall below evidence based recommendations (Caruso, Zaghini, & Sili, 2016). Unlike their metropolitan counterparts, in rural emergency departments NPs must work to the full scope of their expanded role across all patient acuities (Haines & Critchley, 2009) including those presenting with complex conditions including chest pain. This "generalist" practice may provide explanation as to our ENPs ambivalence regarding self-perceived competence. In metropolitan hospitals, health services are generally provided by dedicated specialist staff, with the ENP service model centred on the delivery of care to patients with minor injury or illness. Dissimilarly, the rural ENP service is required to provide care to patients that encompasses a wide variety of diagnoses. The rural ENP service is required to have wide knowledge and skills to deliver safe and effective care that may preclude a mastery in any particular area and thus, impact on reported self-perceived competence.

6.3 PROCESS DIMENSION

Continuing to the next dimension in Donabedian's framework, *Process* refers to what is actually done in the giving and receiving of health care. Although the process of care for patients presenting to ED with chest pain is well-described, review of the literature identified that knowledge was limited to the metropolitan context. This research was focused on the effectiveness of ENPs in the management of patients presenting with chest pain in rural ED settings. Accordingly, to enable

this evaluation using the Donabedian framework, there was a requirement to establish the evidence for the processes of care for the rural cohort of patients.

The preliminary study (see Chapter 3) served to provide insight into the processes of care for patients presenting to rural EDs with chest pain. The results of the retrospective study described for the first time the prevalence and significance of rural chest pain ED presentations. This study provided groundwork for the subsequent research by establishing knowledge of the processes of care and highlighted the significance of risk stratification strategies for patients presenting to rural EDs with chest pain. The use of the current clinical guideline for the management of patients with suspected or confirmed ACS (Chew et al., 2011) necessitated a high proportion of patients being admitted for further observation and management.

In response to these findings and after review of the contemporary literature, the need for a systematic appraisal of the evidence for risk stratification tools was identified. Whilst other studies (Backus, et al, 2011; D'Ascenzo, Biondi-Zoccai, Moretti et al, 2012; Yan et al., 2007) have compared the diagnostic accuracy of risk stratification tools for patients with diagnosed ACS, this was the first review that has compared risk stratification tools for the cohort of patients with undifferentiated chest pain presenting to ED. Our goal was to compare the commonly used risk stratification tools used to predict the risk of MACE for patients presenting to rural EDs with chest pain. No evaluation of risk stratification tools for ACS in rural populations were identified. The systematic review research findings were that:

- A higher proportion of patients could be safely discharged from the ED through use of the EDACS-ADP,
- The EDACS-ADP was the most effective discriminatory tool for patients presenting to rural EDs with undifferentiated chest pain, and
- There was a lower economic burden for health services through utilisation of the EDACS-ADP.

In finding these results, in the absence of rural research in this field, the determination of the EDACS-ADP as the most effective risk stratification tool was contingent on the use of data from studies from metropolitan EDs. In the rural setting, there is a reliance on point of care testing for which the EDACS-ADP has not

been validated. Additionally, acceptable rate of MACE in discharged patients was determined using the results from a survey of ED clinicians (Than, Herbert, Flaws et al., 2013). Despite these limitations, the systematic review is now the most up to date information on the state of the science reporting the diagnostic accuracy of risk stratification tools for use in the rural ED cohort of patients presenting with undifferentiated chest pain.

Having established the foundation evidence for the processes of care, for patients with chest pain presenting to rural hospitals with chest pain, the prospective cohort study provided insight into the effectiveness of ENP service through the evaluation of adherence to guidelines and diagnostic accuracy. The aim of clinical guidelines is to improve the quality and safety of care through the use of evidence based practice (Thomas et al., 1999). Few studies have examined the extent of adherence to clinical guidelines in the emergency environment (Ebben et al., 2013). Consequently, little is known about guideline use in the Australian context and in particular in the rural setting. Our observation that there was a high level of adherence, with both service models achieving a minimum of 64% compliance with ACS guidelines, describes for the first time the extent to which recommended guidelines are followed and establishes the current benchmark for rural health services. Although there are no previous studies have directly examined ED guideline adherence in ACS, comparison with other research supports the finding of a high level of guideline adherence for the service models in our study. The level of adherence was nearly double that for the management of adult patients presenting to an Australian metropolitan ED with asthma (Doherty et al., 2007). More than 82% of participants in our study were administered aspirin according to the evidence-based guidelines. Similarly, this proportion is more than double that found in a 2007 cross-sectional study of 544 emergency departments in the USA that aimed to evaluate the proportion of patients receiving guideline recommended care in acute coronary syndrome and found that aspirin was administered to only 40% of patients in the study (Pham et al., 2007).

More specific to the goals of this research, the ENP service model was associated with a higher level of diagnostic accuracy and adherence to guidelines for the management of patients presenting with chest pain. Although the standard care model achieved a high level of adherence to the guidelines, in the majority of areas

the proportion of patients receiving guideline-recommended care was lower than that achieved by the ENP service model. All patients presenting with chest pain who were managed by the ENP model of care were administered oxygen and aspirin according to guidelines. In contrast, the standard care model achieved levels of 82.1% and 89.3% compliance respectively. Similarly, higher rates of adherence for the use of diagnostic investigations and therapeutic interventions were demonstrated for the ENP service model. For example, greater than 80% of patients with diagnosed ACS in the ENP cohort were administered clopidogrel and enoxaparin, whilst the standard care model achieved 64.3% and 71.4% respectively. An explanation for the standard care model achieving lower levels of compliance with evidence-based guidelines could be that the medical officers studied may have preferred to exercise professional autonomy in making clinical judgements based on personal experience, which has been found to influence adherence to emergency department guidelines (Ebben, Vloet, de Groot, & van Achterberg, 2012). This conclusion was also supported by a recent systematic review of guideline adherence for surgical antibiotic prophylaxis that reported physicians routinely used their "own guidelines" which were shaped through personal experiences (Gouvêa, Novaes, Pereira, & Iglesias, 2015).

The ENP model of achieved a higher level of diagnostic accuracy of electrocardiograph interpretation (91.7%) than the standard care model (82.8%) in this study. This study was the first to evaluate the diagnostic accuracy of emergency nurse practitioner service in complex investigation. Previous investigation of diagnostic accuracy of the ENP service has been primarily conducted in the area of minor injury and illness with studies reporting on missed injury and fracture rates. Several studies have demonstrated no difference between ENP service and medical care in the accuracy of x-ray interpretation (Colligan et al., 2011; Lee et al., 2014; van der Linden et al., 2010). However, others have found a similar higher level of diagnostic accuracy for ENP service (Lau et al., 2013; Thompson & Meskell, 2012), with ENPs having a lower rate of missed fractures and false positive results than the medical officers studied.

For our study, no participant who was managed in the ENP service model had an unplanned representation within seven-days. Participants in our study were 2.4 times more likely to have an unplanned representation within seven-days if managed

by the standard service model (Fisher's exact test, p=0.289). The unplanned representation rate (6.6%) for this study was higher than found for the preliminary study (0.6%). Whilst studies have demonstrated no difference (Colligan et al., 2011; Dinh et al., 2012) in unplanned representation rates for patients managed by ENP service model (compared with the traditional medical model), our study supports others (Feetham et al., 2015; Nash et al., 2007) in finding it was less likely that participants will represent to the emergency department.

Assessment of the process dimension, such as adherence to evidence-based guidelines and diagnostic accuracy, is fundamental to the evaluation of the safety and quality of the ENP service model, as it provides objective evidence of the care that is provided. However, this evaluation only addresses a part of the assessment of the effectiveness of the model. To provide further evidence, examination of the outcomes of the care was required.

6.4 OUTCOME DIMENSION

For this study, we used evaluation of the ENP service model on service indicators, satisfaction with care, quality-of-life and functional status to determine the safety and quality of ENP care in terms of Donabedian's dimension of *Outcome*, the effects of health care on patients and populations.

This study found no significant difference between the ENP model and the standard care model with regard to the organisational outcomes of waiting times, length-of-stay and did-not-wait times. This finding was consistent with the most recent research that has evaluated ENP service on these indicators in Australian EDs (Jennings, Gardner, et al., 2015b). Although other studies have demonstrated a reduction in the length-of-stay for patients managed by an ENP service (Colligan et al., 2011; Considine et al., 2010), these findings are limited because there was no standardised definition for the clinician groups studied. In these studies (Colligan et al., 2011; Considine et al., 2010), doctors with lower levels of experience required "sign-off" by a senior colleague and there were marked differences in the responsibilities of these clinicians whilst the ENP comparator had lower levels of interruption with a clear focus on the management of minor injury and illness. Furthermore, many of these studies were based on retrospective audit data rather than prospective studies (Ducharme et al., 2009; Jennings et al., 2008, 2013). Our

prospective cohort study avoided these limitations and the majority of patients that were managed in the standard care model had a senior medical officer as the lead clinician.

The majority of participants (88.5%) were "highly satisfied" with the overall quality of care. In addition, our study found that these high levels of satisfaction with care were maintained at follow-up evaluation; 93.2% of participants were "highly satisfied". Similar high levels of patient satisfaction with the ENP service model have been demonstrated by others (Dinh et al., 2012; Jeanmonod et al., 2013; Lutze et al., 2013; Nash et al., 2007). Pursuing this further, a higher level of rapport was correlated with ENP service when compared with the standard care model. Participants managed by the ENP service model reported that they could discuss their concerns and be listened to carefully, explanations by the clinician were easily understood and participants felt involved in their health care decision making. In the same way Jeanmonod, et al. (2013) also found that the majority of patients of an ENP felt cared about, were kept aware of tests and had their problems and follow-up explained. Using a well-designed survey to evaluate the full dimensions of the ENP role that included the substance of nursing care and its influence on patient outcomes, Thrasher & Purc-Stephenson (2008) report similar findings of this high satisfaction with care with ENP service.

Participants managed by the ENP service were less definite about being provided with information regarding treatment choices, and less likely than those managed in the standard care model to be consulted on treatment preferences. This finding was unexpected, and is concerning for the ENP service model. Whilst the role is rooted in the values and goals of professional nursing, as the service merges the medical and nursing aspects of their role there is a possibility of losing sight of these goals, particularly patient centred care (Dawood, 2005). Patient-centred care seeks to empower patients and their families (Gluyas, 2014) and functions within a framework that considers patient values, preferences and aspirations as equally important in the patient care process (Weaver, 2015). Evidence based medicine places importance on knowledge being derived from research, however some put forward that this concept conflicts with patient-centred care (Burman, Robinson, & Hart, 2013; Weaver, 2015) because of concerns that scientific advances have contributed to impersonal, fragmented clinical care (Weaver, 2015). It is easier,

especially in complex clinical presentations where there is little time for long discussions and detailed presentations on options (Woolf, Chan, Harris, & Sheridan, 2005), for clinicians to rely on established clinical guidelines and to ignore patient's "uniqueness" (Timmermans & Mauck, 2005) by not including patient preference (Burman et al., 2013) in the delivery of care.

The use of the Donabedian framework which emphasises the interdependence of the structure-process-outcomes dimensions, provides another explanation for this finding that patients of the ENP cohort were less likely to report autonomy than those managed by in the standard care model. In our evaluation of the process dimension for this research, ENP service was associated with a higher level of adherence to guidelines for the management of patients presenting with chest pain. These guidelines provide guidance on management and are informed by evidence regarding the benefits and harms, possibly producing conflict in ethical behaviour for clinicians (House et al., 2015). Ethical behaviour is central to professionalism and includes the four principles of autonomy, beneficence, nonmaleficence and social justice (Draper, Dawson, & Ashcroft, 2007; House et al., 2015). The principle of beneficence means to act for the benefit of others (Rogers, 2002), to prevent harm and balance the benefits against the risk (Draper et al., 2007). Although all four principles are important for ethical decision making, beneficence has been noted as being most influential because the harm that it requires us to prevent may be most substantial (Draper et al., 2007). Acting for the good of the patient necessitates the use of guideline recommended treatments that have the potential to improve outcomes by promoting the use of interventions that have been demonstrated to be of benefit and discouraging ineffective interventions (Rogers, 2002). Although patient autonomy is a fundamental tenet of medical ethics, respect for patient choice is at odds with the prescriptive nature of guidelines. The patient is free to refuse the recommended intervention, but the power of autonomy is restrained to a predetermined range of options (Rogers, 2002).

6.5 STRENGTHS AND LIMITATIONS OF THE RESEARCH

The research benefits from a sound methodological approach to the evaluation of the ENP service and used a well-known, widely used theoretical framework that allowed for the study of multiple variables in the examination of the service model.

The preliminary study was the first to investigate the demographic and clinical characteristics of patients presenting to rural emergency departments with undifferentiated chest pain. In conjunction with the systematic review, this research provided knowledge on the processes of care for rural patients with chest pain and addressed a significant gap in the contemporary literature.

The systematic review that was conducted to examine the diagnostic accuracy of risk stratification tools for use in the rural cohort of patients presenting to ED with chest pain used rigorous scientific methods. The studies included in the review were all prospective allowing increased applicability and reliability of the study. A validated tool (QUADAS-2) was used for the quality assessment of studies included in the systematic review.

There has been no previous enquiry into the effectiveness of rural ENP service in the management of a complex ED presentation; the results of this study are pivotal for further evaluation of the service model. The prospective design of the nested cohort study incorporated strategies that were included to reduce bias and increase the validity of the results. The validity of the study was also strengthened through publishing the study protocol prior to the commencement of the research which promoted transparency, openness and reproducibility of the study. Using the Donabedian framework facilitated an objective and systematic assessment of the safety and quality of the service and provides direction for future research. The study design further strengthened by the use of validated and well tested tools to evaluate the multiple dimensions of the ENP service, including the substance of nursing care and its influence on patient outcomes. The study design avoided the limitations of previous ENP research by using qualified ENPs working to the full scope of their role without a reliance on comparison with junior doctors who don't share the advanced skills or practice privileges afforded to ENPs. Further, use of a blinded assessor (the "gold standard") with specialist emergency qualifications in the measurement of diagnostic accuracy of ECG interpretation supports the credibility of our findings.

As with all research there were limitations for this research. There was a small potential for missed studies using the strategy developed for the systematic review, particularly by the limiting of included studies to English only. Secondly, the preliminary study used a retrospective design that may have been affected by

incomplete or inaccurate data. Finally, there were issues with research governance at a study site level and significant problems with patient recruitment for the prospective cohort study leading to an underpowered study.

Although most of the limitations above are common to research, the most significant limitation of this thesis relates to the small sample size for the cohort study. The critical issues and problems that were encountered during the study are analysed and discussed in the following manuscript.

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The following is the format for the required declaration provided at the start of any thesis chapter which includes a co-authored publication.

The authors listed below have certified* that:

1. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
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In the case of this chapter:

Perils and pitfalls in conducting rural health services research: a biographical case study

Submitted to *Australian Health Review* July 2016

Contributor	Statement of contribution*
Tina Roche 15/09/16	Drafting of manuscript, final approval of manuscript
Glenn Gardner	Drafting of manuscript, final approval of manuscript
Leanne Jack	Drafting of manuscript, final approval of manuscript

Principal Supervisor Confirmation

I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

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6.5.1 Publication – Case study

Perils and pitfalls in conducting rural health services research: a biographical case study

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Submitted to *Australian Health Review* July 2016

Journal Metrics	
Impact factor	0.820
H index	30
SCImago Journal Rank (SJR)	0.39 Q2

Abstract

Health service reforms designed to increase access to health care for rural communities have included innovative service and workforce models. There is a paucity of evaluation studies into the effectiveness of these innovations in terms of safety and quality in patient care. Clearly, there is a need for rigorous appraisal to ensure that health service improvement measures are beneficial to the health and well-being of people who live in rural areas. However, conducting evaluation research to achieve this level of examination of rural health service innovation has hitherto unexamined challenges. The aim of this biographical case study was to build knowledge of the critical issues and problems encountered for the conduct of outcome focused, rural health services research. This paper presents a narrative

critical analysis of the problems encountered during the **Ma**naging chest **P**ain in **R**ural **E**mergency **D**epartments (MaP-RED) study.

Introduction

Globally, emergency departments (EDs) have experienced overcrowding and an increased demand for services, with the greatest increase found in high acuity presentations (Lowthian & Cameron, 2012; Toloo et al., 2011). Rural EDs have been particularly impacted by this trend. Whilst major Australian metropolitan EDs experienced a 15% growth in ED presentations, regional areas experienced a 24% increase in the period 2001-2002 to 2007-2008 (Toloo et al., 2011). Recently, there has been a call for reforms to improve access through use of new service models for the delivery of effective, appropriate and sustainable care (Standing Council on Health of the Australian Health Ministers Conference, 2012). In rural areas where there is often no available alternative in health care, there is an essential and urgent need for rigorous appraisal of the quality and safety of rural health innovations.

The aim of this biographical case study was to build knowledge of the critical issues and problems encountered for the conduct of rural health service innovation outcomes research.

Background

The evaluation of rural health service initiatives is often neglected with funding for rural research being favoured for the ostensibly more important concerns of fiscal sustainability, structural frameworks and access (Rosenblatt, 2001). The Australian Government Rural Health Workforce Strategy was established under the 1996/1997 Budget (Gausia et al., 2015) as a response to inequalities in the health outcomes of the rural population caused through limited access to health services and an unequal distribution of health professionals (Humphreys et al., 2006). Crucial shortages of doctors and concerns about the sustainability of health services have also lead to the majority of rural funding being invested in resources and training for rural health practitioners. Research to date has been primarily focused towards study of rural workforce issues, health services policy (Gausia et al., 2015) and collection of general epidemiological data (Patterson, 2000). With limited funding for health services research there are large gaps in the research that has examined the outcomes of rural health service innovations.

Whilst previous research was important for beginning evaluation of rural health services, research questions now need to evolve from the processes of care to the outcomes of that care which has now ostensibly become more accessible through service reform initiatives. Clearly then, in acknowledging the lack of high quality evidence regarding the effectiveness of rural health services, there is a requirement to evaluate the safety and quality of health care.

Methodology

The case study presents a narrative critical analysis based on a single biographical case study of the researchers' observations of a prospective cohort research study. Biographical research is becoming increasingly significant as a research approach. According to Roberts (2002) this surge of interest is related to many factors, one of which is the growing interest in people's experience of common social situations and how best to reveal it. Furthermore, biographical researchers take a pragmatic stance in research practice; often the tellers may be the only witnesses to specific experiences in which case the narrative report needs a process whereby their accounts can be checked against other evidence (O'Neill, Roberts, & Sparkes, 2015). In this study the researcher is also the participant, accounts and assertions in this report will be supported by published research and reference to standardized processes.

For this case, the lead researcher was a rural clinician who was undertaking Doctor of Philosophy study which was centered on the evaluation of the effectiveness of rural health service innovations. The data reported for this case study are garnered from the experiences of the researcher during the conduct of a prospective cohort study.

Background of the prospective cohort study

The **Ma**naging chest **P**ain in **R**ural **E**mergency **D**epartments (MaP-RED) study was designed to examine the effectiveness of ENP service compared to standard medical care in the rural environment for patients presenting with undifferentiated chest pain. The study protocol has been previously published (Roche, Gardner, & Lewis, 2015). In summary, the study design was a prospective longitudinal nested cohort study that examined multiple outcomes for adult patients presenting to three rural EDs in Queensland, Australia with a presenting complaint of atraumatic chest

pain. An *a priori* sample size calculation estimated that the study required a sample size of 384 patients. Using the results from our preliminary study (Roche, Gardner, & Lewis, 2014) we anticipated a six-month period for data collection; however, there were critical issues with participant recruitment necessitating conclusion of the study prior to achieving the requisite sample.

Results

Human research ethics and site governance issues

The MaP-RED study used a multisite approach in order to increase sample size whilst conducting research within the time frame of a PhD candidature. The jurisdictional Human Research Ethics Committee (HREC) process for multisite studies is streamlined. A single HREC application is submitted to one committee for review for all study sites. Following HREC approval and before recruitment and data collection can commence, researchers are required to secure site-specific approval from each participating site. This process involves a separate approval process including sign-off by local representatives at each health service before submission to the local research governance office (RGO). This officer then seeks the approval of the health district chief executive officer. In this research at one of the sites this approval was delayed for four months as the position of RGO for that district had been vacant with no other staff having authority for this process. Consequently, the inclusion of this site in the study was aborted necessitating the identification and recruitment of another suitable site, and further site-specific approval application. The outcome of this process for the research in this Case was an eleven-month delay to commencement of patient recruitment and data collection.

Issues of research culture in rural health settings

There was initial enthusiasm and agreement from the clinicians for the MaP-RED study at the participating rural sites. However, without a continued and sustained research lead presence, the sites lacked a culture to sustain involvement and maintain the momentum of the research. Across all sites there was lack of research experience and scant previous exposure to the processes of research. Despite clinicians initially agreeing involvement in the study and after these clinicians having extensive onsite training and education in study processes, the recruitment did not proceed as anticipated. Even though there was an offer of

payment per patient recruited to the study, participant recruitment to the study could not be stimulated. The outcome of this was an underpowered study that compromised the validity of the study findings.

Issues with geographical distances

The three participating sites for the MaP-RED study were separated by a distance of 300 kilometres. At the commencement of the study and at a further time during the conduct of the study, the lead researcher travelled to each site to ensure training and address problems for each of the sites local research staff. Any additional onsite support for those further away was prohibitive. For each of these site visits the researcher was required to meet the travel and accommodation costs, as well as take time away from her PhD studies. The outcome of this was limited involvement by the researcher in the data collection processes for the study.

Discussion

The ethical governance processes proved challenging for this research and significantly impacted the conduct of an otherwise well-designed study. Our experiences with ethical review and site-specific approval mirror that of others. Christie, Gabriel, & Dear (2007) reported significant delays in the conduct of their trial through ethical administrative delays caused through the time need to prepare for submissions (and obligate resubmissions) and delays while applications were reviewed and approved. Similar issues were documented by Boult, Fitzpatrick, Maddern, & Fitridge (2011) who also noted that extended scrutiny at individual sites to determine local research requirements severely hampered research progress.

The critical issue for the study were the problems encountered through a lack of rural research culture. Problems with participant recruitment for MaP-RED were identified early in the conduct of this research. Funding was available to increase the rate of participant recruitment, however this strategy did not increase participant numbers. Ultimately, it was difficult to maintain study momentum and there was a high turnover of research assistants at each site. The consequence of this was that although the study had a sound methodological basis, it was underpowered to detect significant differences between service models. There are limited skilled staff and the majority of rural clinicians report not having an incentive to carry out research (Koschel et al., 2012). A lack of time and research culture in clinical work settings,

limited access to research expertise and networks and minimal organisational support are barriers to a strong research culture which contributes to limiting research activity (Pager, Holden, & Golenko, 2012; Schmidt & Kirby, 2016). Still others have found that the presence of a research lead increased local research activity that was evidenced by a higher level of individual involvement in data collection, writing reports or publications and applications for research funding (Williams et al., 2015).

Enquiry into the the extent to which rural health professionals are actually interested, involved and undertaking research activities is urgently required. The lack of specific knowledge about the barriers and enablers relating to research engagement in rural health services limits our understanding of what is required to foster a strong research culture. Without a scientific foundation it is challenging to design research capacity building initiatives and engage organisations to commit resources towards this undertaking. Rural health services need to provide tailored strategies to assist with the development of research capacity to engage the local workforce in research activities. Although workforce shortages and professional isolation may impact on the development of a strong research culture, suggested solutions include a formal mentorship and research support arrangements; there is a need to ensure that rural clinicians have the skills, time to perform research activities and networks with other researchers (Carla Patterson, 2000). The cost-effectiveness of this strategy may make this unachievable but it is plausible that only a select number of staff may need to be highly engaged in research activities.

Future directions for rural research includes needs to include mentorship, lobbying for increased funding and a robust national strategic plan. This plan must include processes to develop rural research culture and a simplified governance structure for rural research.

Conclusion

Although the MaP-RED study was well conceived, employed rigorous research methods, established sample feasibility and benefited from the use of an appropriate study design, the issues reported and discussed in this case study contributed to problems with patient recruitment ultimately led to an underpowered study. As demonstrated by this biographical case study, there are problems that with regard to the impediments to rural health outcomes research that create an impasse. Without access to knowledge, support and resources, research does not occur. Until these

issues start to be addressed rural health services may not see the value of research in action and may not support research activities. Although reforms may have improved access to rural health services, there is limited evidence that examines the safety and quality of that care. The rural population, policy-makers and all members of the health care team are therefore poorly served by the paucity of rural outcomes research. The fundamental goal for rural health services research is to improve the health and well-being of the people who live in rural areas. The challenge for researchers is to provide empirical evidence of effectiveness of service innovations and the challenge for policy makers and research funders is to enable a research culture and evidence informed practice in rural health services.

END OF SUBMITTED MANUSCRIPT

References for the submitted manuscript are included in the thesis reference list

6.6 SUMMARY

This Chapter presented the results of this research using a Donabedian framework to guide this discussion. The aim of this research was to provide evidence of the safety and quality of the ENP service in the management of patients presenting to rural hospitals with chest pain. This research serves as the first enquiry into the effectiveness of this service level outside of the metropolitan context and beyond the scope of minor injury and illness presentations. The research has contributed knowledge to the Structure of the rural ENP service and the Process of care for patients presenting to rural hospitals with chest pain that was not previously known. The Outcome of ENP service was demonstrated to be comparable to that of the standard model of care.

Chapter 7: Conclusion & Recommendations

Gardner (2004) has suggested that the nurse practitioner level of health care is one of the most important advancements for nursing in the past 30 years, creating an opportunity for significant Australian health services reform. Nurse practitioners possess high-level skills and are at the highest level of the nursing hierarchy. Whilst the timely delivery of quality patient care in the ED is one of the most important service indicators, there are significant gaps in the research that has evaluated the ENP service model on the outcomes and processes of care. There is scant research that has evaluated ENP service in the rural context, with contemporary research limited to evaluations of the model in the minor injury and illness context. In my role as endorsed emergency nurse practitioner working at a rural hospital, my challenge is to ensure provision of health care that is safe and of the highest quality to patients. In my role as a researcher, my challenge is to provide evidence of safety and quality the service innovation.

Current research indicates that nurse practitioners are effective in the management of patients presenting to metropolitan emergency departments with minor injury and illness. The beneficial effect of an ENP service in meeting organisational goals or key performance indicators is evidenced in the influence of the service. Shorter length of stay and waiting times for patients managed by an ENP service and a lower proportion of patients who left without being seen have been demonstrated. High levels of patient satisfaction and the acceptability of the ENP service have been clearly established without reservation. The majority of patients find ENPs competent in providing care and are satisfied with their overall care. The clinical effectiveness of the ENP service has been established through study of the quality of referral to other health professionals, therapeutic interventions and the ordering and interpretation of diagnostic investigations. ENPs have been shown to effectively use clinical tools that support the provision of evidence-based health care with a diagnostic accuracy that was at least equivalent to medical doctors.

Whilst the findings of this study seems to confirm the work of these researchers, the function of my research was that it contributes to evolving knowledge about the effectiveness of the rural ENP service in the management of patients presenting with complex and high acuity health needs, a hitherto scientifically unknown area. As a clinician, I was confident that the quality of this care was comparable to that of the standard model of care. This study validates this belief. The **Ma**naging chest **P**ain in **R**ural **E**mergency **D**epartments study, a prospective longitudinal nested cohort study, investigated the safety and quality of the ENP service in the management of patients presenting to rural emergency departments with a complex health care condition. The study used validated tools in the assessment of the Donabedian structure-process-outcome dimensions. Donabedian (1966) contended that the quality and safety of health care can be assessed through examination of structure, process and outcome; each is necessary but not sufficient alone for appraising care as being high quality. During the process of the research many worthwhile and important discoveries have been made about the structures, processes and outcomes of care for this cohort of patients. The structures for the rural ENP service model, through advancement of the rural nursing role, appear to support the delivery of a safe and quality service. For the process dimension, the ENP service model was associated with a higher level of diagnostic accuracy and adherence to guidelines than that of the standard care model. No differences between the service models was found for the outcomes of care.

In making these findings, the conduct of the research was not without problems. Significant barriers to patient recruitment for rural research exist that were not previously appreciated by the researcher. Despite best laid plans, including a rigorous study methodology, these issues ultimately led to an underpowered study. These impediments to rural health research severely affect the delivery and evaluation of health care to the rural population. The central goal for rural health services research is to improve the health and well-being of its people. The challenge for health services is to provide evidence of the effectiveness of the care provided.

7.1.1 Recommendations arising from the research

The following recommendations are made:

1. The systematic review of diagnostic accuracy of risk stratification tools identified a tool that could safely discharge a higher proportion of patients presenting with chest pain from the ED.

   It is recommended that a randomised controlled trial is undertaken to evaluate the performance of the EDACS-ADP for patients presenting to rural EDs with chest pain.

2. The acceptable missed event rate for major adverse cardiac event rates that was used in the determination of the EDACS-ADP as the most discriminatory risk stratification tool for rural ED patients with chest pain was determined using data for metropolitan emergency physicians.

   It is recommended that the acceptable major adverse cardiac event rate for rural clinicians and patients be established

3. The Donabedian Structure-Process-Outcome framework was demonstrated to be beneficial in the evaluation of the service model in the rural context by facilitating an objective and systematic assessment of the safety and quality of ENP service through identification of multiple variables.

   It is recommended that the Donabedian Structure-Process-Outcome framework be used for further evaluations of the rural ENP service to allow between-study comparisons of the quality and safety of care of the service.

4. The prospective nested cohort study methodology in the evaluation of an existing ENP service model is a powerful study design that was demonstrated to describe and analyse the association between ENP service and multiple outcomes simultaneously.

   It is recommended that further enquiry of the Structure, Processes and Outcomes for patients presenting to rural hospitals with undifferentiated chest pain be undertaken using a similar high-quality study design,

5. Issues of research culture in rural health services and human research ethics and site specific governance impacted on the study processes.

   It is recommended that:

   (i) Research governance processes be streamlined for multisite rural research projects,

   (ii) Enquiry be made into the barriers and enablers relating to research engagement in rural health services,

   (iii) Research capability is enhanced for rural health service research through formal mentorship and research support arrangements,

   (iv) Policy makers increase funding for rural health services research; and,

   (v) Health services invest in activities to ensure local clinicians have the skills, time to perform research activities and networks with other researchers.

6. The research findings provide foundation evidence for the rural ENP service innovation as efficient and comparable to that of standard care in the current contemporary rural ED setting.

   It is recommended that:

   (i) Additional multisite prospective studies with larger patient numbers be undertaken to provide further support for the rural ENP service model, and

   (ii) The findings of the prospective nested cohort study be disseminated to clinicians, health services and policy makers.

In closing, this study has provided beginning evidence of the quality of rural ENP service. The research findings have served to address gaps in the literature regarding the safety and quality of ENP service in the delivery of care to patients with complex health needs in the rural setting. They are a foundation from which to build upon. Hence my inquiry into this area, rather than concluding with this dissertation, is just beginning.

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Appendices

Appendix A MEDLINE search strategy

Databases included in electronic search MEDLINE (January 2011 to January 2015) EMBASE (2011 to 2015)

Medline search strategy
1 TS=chest pain OR TI=chest pain OR MH=chest pain OR MT=chest pain
2 TI=(emergen* NEAR/3 ("treatment$" OR "centre$" OR "center$" OR "unit$" OR "room$1" OR "department$" OR "service" OR "physician$" or "medicine" or "care" OR "ward$1")) OR TS=(emergen* NEAR/3 ("treatment$" OR "centre$" OR "center$" OR "unit$" OR "room$1" OR "department$" OR "service" OR "physician$" or "medicine" or "care" OR "ward$1"))
3 MH=(Emergency Medical Services OR Emergency Medicine OR Emergency Service, Hospital OR Emergency Treatment OR Triage)
4 MH:exp=(Angina Pectoris OR Myocardial Infarction)
5 TI=(acute* NEAR/2 ("coronary" OR "cardiac" OR "myocardial" OR "heart") NEAR/2 ("syndrome$" OR "infarct$"))
6 MH=(Diagnosis OR Diagnosis, Differential OR Diagnostic Errors OR Patient Discharge OR Patient Readmission OR Outcome "and" Process Assessment (Health Care))
7 MH=(Risk Assessment)
8 TS=(risk NEAR/4 (stratif$ OR score$))
9 #5 OR #4 OR #1
10 #3 OR #2
11 #10 AND #9
12 TS=(risk$ OR predict* OR prognos$)
13#12OR#7
14 #13 AND #11
15 TS=(prospective$ OR cohort$ OR evaluat$ OR validat$ OR comparative$)
19 #15 AND #14

Appendix B HREC Approval letter – Audit Study

13/QTHS/158_3
Human Research Ethics Committee
Medical Services Support Unit
07 4433 1140

Queensland Government

Townsville
Hospital and Health Service

10th December 2013

Tina Roche
68 Greenup Street
Stanthorpe
QLD 4380

Dear Mrs Roche,

HREC reference number: HREC/13/QTHS/158
Project title: A retrospective multi-centre descriptive observational study of patients presenting to rural emergency departments with undifferentiated chest pain

RE: Amended Approval Letter

Thank you for submitting a response to the Committee's concerns regarding the above project on 25/10/13, which was considered by the Townsville Hospital and Health Service Human Research Ethics Committee (HREC) Chairperson on 19/11/2013.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition with specialty and affiliation with the Hospital (Attachment I).

I am pleased to advise that the Human Research Ethics Committee has granted approval of this research project. The documents reviewed and approved include:

Document	Version	Date
Response letter		22.10.13
Data Abstraction Instrument		
Application		13.09.13
Study Protocol		
Curriculum Vitae – Tina Roche		

The research project has ethical approval for the following sites:
Stanthorpe Health Services
Mount Isa Health Services
Gatton Health Services

You are reminded that this letter constitutes ethical approval only. There are two further steps you must complete prior to commencing your project:

Please be aware that you are also required to obtain Public Health Act approval for the use of identifiable or potentially re-identifiable confidential health information without the written consent of the person to whom the data relates. Refer to the website below for information on the Public Health Act and the application process:
http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp

A copy of this approval must be submitted to the Health Service Research Governance Officer/Delegated Personnel with a completed Site Specific Assessment (SSA) Form, supporting study documents and the Public Health Act approval letter for authorisation from the CEO or Delegate to conduct this research at the approved sites. Refer to the local THHS website for further information on Site Specific Assessment:
http://qheps.health.qld.gov.au/tville/district-executive/medical-services/mssu-ethics.htm

Townsville Hospital and Health Service
Human Research Ethics Committee
Telephone +617 4433 1140
Email TSV-Ethics-Committee@health.qld.gov.au

The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
Unforeseen events that might affect continued ethical acceptability of the project.
Serious Adverse Events must be notified to the Committee as soon as possible. In addition the investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.

Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major amendments should be reflected in a revised online application form (accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised application form, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC coordinator as per standard HREC SOP. Further advice on submitting amendments is available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r (by-passing the HREC).

Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly the HREC for review and, once HREC approval has been granted, then submitted to the RGO.

Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the HREC coordinator. These should include a cover letter from the principal investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.

The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.

The Health Service administration and the Human Research Ethics Committee may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on hospital premises or claiming any association with the Hospital; or which the Committee has approved if conducted outside any of the approved sites.

HREC approval is valid until 31/03/2014.

Should you have any queries about the HREC's consideration of your project please contact me on (07) 4433 1140. The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Once site specific authorisation to conduct the research has been granted, please complete the Commencement Form (Attachment II) and return to the office of the Human Research Ethics Committee.

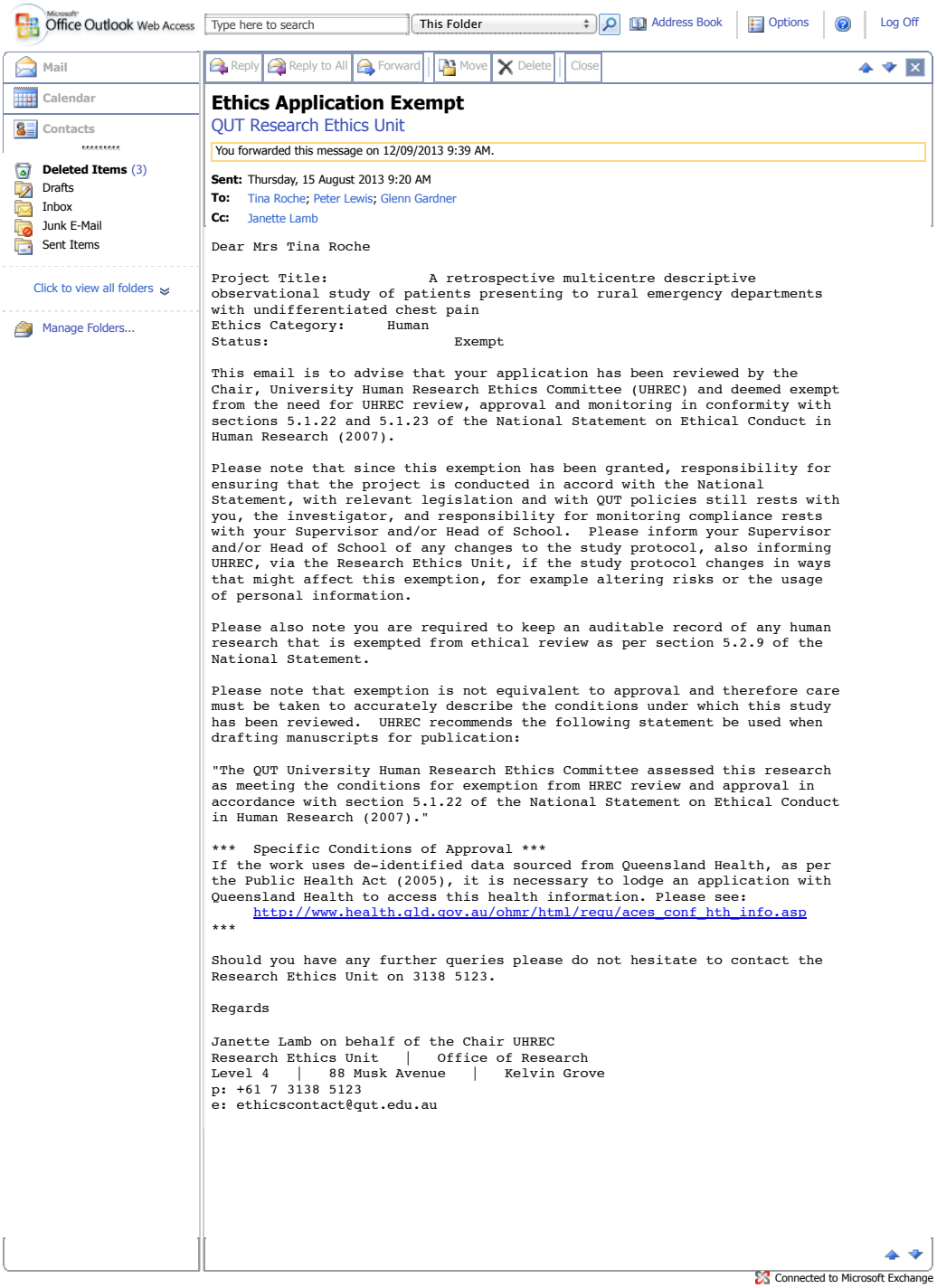
The HREC wishes you every success in your research.

Yours sincerely

A/Prof Andrew Johnson
Chairperson
Townsville Hospital and Health Service
Human Research Ethics Committee

Townsville Hospital and Health Service
Human Research Ethics Committee
Telephone +617 4433 1140
Email TSV-Ethics-Committee@health.qld.gov.au

Appendix C QUT Ethics Exemption letter – Audit Study



Office Outlook Web Access | Type here to search | This Folder | Address Book | Options | Log Off

Mail
Calendar
Contacts

Deleted Items (3)
Drafts
Inbox
Junk E-Mail
Sent Items

Click to view all folders
Manage Folders...

Reply | Reply to All | Forward | Move | Delete | Close

Ethics Application Exempt

QUT Research Ethics Unit

You forwarded this message on 12/09/2013 9:39 AM.

Sent: Thursday, 15 August 2013 9:20 AM
To: Tina Roche; Peter Lewis; Glenn Gardner
Cc: Janette Lamb

Dear Mrs Tina Roche

Project Title: A retrospective multicentre descriptive observational study of patients presenting to rural emergency departments with undifferentiated chest pain
Ethics Category: Human
Status: Exempt

This email is to advise that your application has been reviewed by the Chair, University Human Research Ethics Committee (UHREC) and deemed exempt from the need for UHREC review, approval and monitoring in conformity with sections 5.1.22 and 5.1.23 of the National Statement on Ethical Conduct in Human Research (2007).

Please note that since this exemption has been granted, responsibility for ensuring that the project is conducted in accord with the National Statement, with relevant legislation and with QUT policies still rests with you, the investigator, and responsibility for monitoring compliance rests with your Supervisor and/or Head of School. Please inform your Supervisor and/or Head of School of any changes to the study protocol, also informing UHREC, via the Research Ethics Unit, if the study protocol changes in ways that might affect this exemption, for example altering risks or the usage of personal information.

Please also note you are required to keep an auditable record of any human research that is exempted from ethical review as per section 5.2.9 of the National Statement.

Please note that exemption is not equivalent to approval and therefore care must be taken to accurately describe the conditions under which this study has been reviewed. UHREC recommends the following statement be used when drafting manuscripts for publication:

"The QUT University Human Research Ethics Committee assessed this research as meeting the conditions for exemption from HREC review and approval in accordance with section 5.1.22 of the National Statement on Ethical Conduct in Human Research (2007)."

*** Specific Conditions of Approval ***
If the work uses de-identified data sourced from Queensland Health, as per the Public Health Act (2005), it is necessary to lodge an application with Queensland Health to access this health information. Please see:
http://www.health.qld.gov.au/ohmr/html/requ/aces_conf_hth_info.asp
***

Should you have any further queries please do not hesitate to contact the Research Ethics Unit on 3138 5123.

Regards

Janette Lamb on behalf of the Chair UHREC
Research Ethics Unit | Office of Research
Level 4 | 88 Musk Avenue | Kelvin Grove
p: +61 7 3138 5123
e: ethicscontact@qut.edu.au

Connected to Microsoft Exchange

Appendix D PHA Approval Letter – Audit Study

Queensland Government

Department of Health

Enquiries to: Vanessa Druett
Health and Medical Research
Preventive Health Unit
Telephone: (07) 3328 9866
Ref QCOS13635/**RD004966**

Ms Tina Roche
68 Greenup Street
STANTHORPE QLD 4380

Dear Ms Roche

Research Title: A retrospective multi-centre descriptive observational study of patients presenting to rural emergency departments with undifferentiated chest pain.
HREC Number: HREC/13/QTHS/158

I am writing to inform you that your request for access to confidential health information for the above project has been approved under the delegation of the Director-General. In accordance with Section 284 of the *Public Health Act 2005* the researchers listed in your application, dated 16 December 2013 can access and use the specified confidential information, providing they act within the limits detailed in your submission.

This approval (RD004966) commences on the date of this letter and is valid to 31 March 2014.

This approval relates to data from the Emergency Department Information System (EDIS) for the period from 01 September 2013 to 31 November 2013.

This approval means that you must undertake the responsibilities and obligations of confidentiality of the information under the provisions of the *Public Health Act 2005.* You must take all reasonable steps necessary to ensure that the confidential information is kept confidential, including storing or disposing of all data, information, documents and associated correspondence in a secure manner. Unauthorised use or disclosure of confidential information may incur a penalty under the laws of the Queensland Government. These obligations include providing notification of any change in the names of persons who will be given the information for the research.

When conducting research within the Queensland public health system, a copy of this Approval Letter must be provided to the relevant Research Governance Officer as part of your research governance application.

Please display this letter and a copy of your application when requesting the confidential information from the relevant data custodian.

You are required to provide an annual progress report and a final report at the completion of your project, to Health and Medical Research, Preventive Health Unit. Templates can be found on the web page http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp

Office
Department of Health
Level 2
15 Butterfield Street
Herston QLD 4006

Postal
HMR – Level 2
PO Box 2368
Fortitude Valley BC QLD 4006

Phone
61 7 3328 9866

Fax
61 7 3328 9115

Should you wish to extend your research project beyond this time or amend the study protocol, you will need to seek approval of these amendments from the approving HREC and re-apply for approval of the release of confidential data. This includes disclosing this information to and recruiting additional people to this project. Please provide a copy of your HREC approval of the amendments when re-applying.

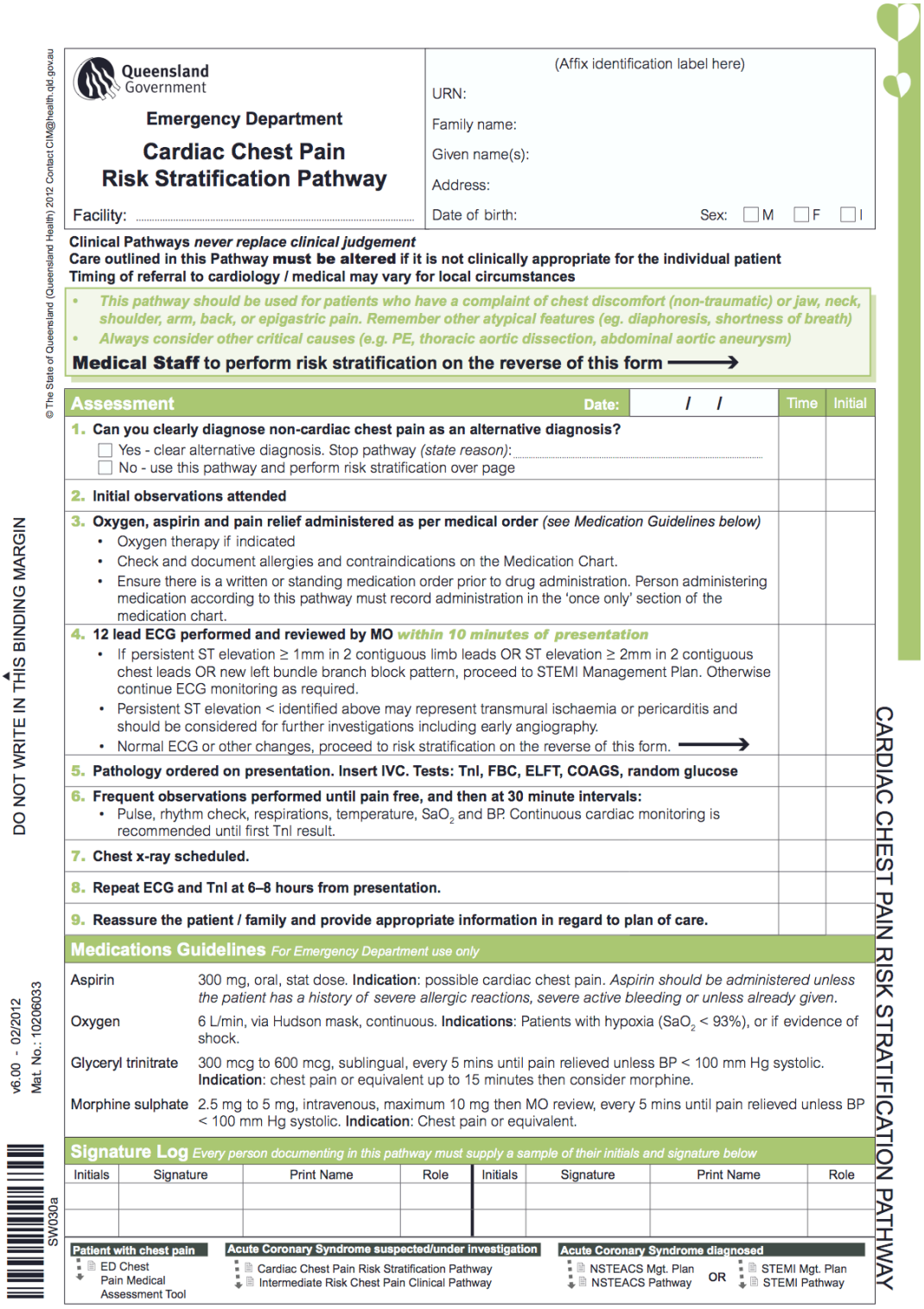
Please feel free to contact Health and Medical Research, Preventive Health Unit on email HMR@health.qld.gov.au or phone 07 3328 9866 if you have any queries on this matter.

Yours sincerely

Kaye Pulsford
Senior Director, Preventive Health Unit
Chief Health Officer Branch
Health Services and Clinical Innovation Division

8/ 9/2014

Appendix E Queensland Health Clinical Pathways



Queensland Government

Emergency Department

Cardiac Chest Pain Risk Stratification Pathway

Facility: .....

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

Clinical Pathways *never replace clinical judgement*
Care outlined in this Pathway must be altered if it is not clinically appropriate for the individual patient
Timing of referral to cardiology / medical may vary for local circumstances

- *This pathway should be used for patients who have a complaint of chest discomfort (non-traumatic) or jaw, neck, shoulder, arm, back, or epigastric pain. Remember other atypical features (eg. diaphoresis, shortness of breath)*
- *Always consider other critical causes (e.g. PE, thoracic aortic dissection, abdominal aortic aneurysm)*

Medical Staff to perform risk stratification on the reverse of this form →

Assessment	Date: / /	Time	Initial
1. Can you clearly diagnose non-cardiac chest pain as an alternative diagnosis? ☐ Yes - clear alternative diagnosis. Stop pathway *(state reason)*: ..... ☐ No - use this pathway and perform risk stratification over page			
2. Initial observations attended			
3. Oxygen, aspirin and pain relief administered as per medical order *(see Medication Guidelines below)* • Oxygen therapy if indicated • Check and document allergies and contraindications on the Medication Chart. • Ensure there is a written or standing medication order prior to drug administration. Person administering medication according to this pathway must record administration in the 'once only' section of the medication chart.			
4. 12 lead ECG performed and reviewed by MO *within 10 minutes of presentation* • If persistent ST elevation ≥ 1mm in 2 contiguous limb leads OR ST elevation ≥ 2mm in 2 contiguous chest leads OR new left bundle branch block pattern, proceed to STEMI Management Plan. Otherwise continue ECG monitoring as required. • Persistent ST elevation < identified above may represent transmural ischaemia or pericarditis and should be considered for further investigations including early angiography. • Normal ECG or other changes, proceed to risk stratification on the reverse of this form. →			
5. Pathology ordered on presentation. Insert IVC. Tests: TnI, FBC, ELFT, COAGS, random glucose			
6. Frequent observations performed until pain free, and then at 30 minute intervals: • Pulse, rhythm check, respirations, temperature, SaO_2 and BP. Continuous cardiac monitoring is recommended until first TnI result.			
7. Chest x-ray scheduled.			
8. Repeat ECG and TnI at 6–8 hours from presentation.			
9. Reassure the patient / family and provide appropriate information in regard to plan of care.			

Medications Guidelines *For Emergency Department use only*

Aspirin	300 mg, oral, stat dose. **Indication**: possible cardiac chest pain. *Aspirin should be administered unless the patient has a history of severe allergic reactions, severe active bleeding or unless already given.*
Oxygen	6 L/min, via Hudson mask, continuous. **Indications**: Patients with hypoxia (SaO_2 < 93%), or if evidence of shock.
Glyceryl trinitrate	300 mcg to 600 mcg, sublingual, every 5 mins until pain relieved unless BP < 100 mm Hg systolic. **Indication**: chest pain or equivalent up to 15 minutes then consider morphine.
Morphine sulphate	2.5 mg to 5 mg, intravenous, maximum 10 mg then MO review, every 5 mins until pain relieved unless BP < 100 mm Hg systolic. **Indication**: Chest pain or equivalent.

Signature Log *Every person documenting in this pathway must supply a sample of their initials and signature below*

Initials	Signature	Print Name	Role	Initials	Signature	Print Name	Role

Patient with chest pain → ED Chest Pain Medical Assessment Tool

Acute Coronary Syndrome suspected/under investigation → Cardiac Chest Pain Risk Stratification Pathway; Intermediate Risk Chest Pain Clinical Pathway

Acute Coronary Syndrome diagnosed → NSTEACS Mgt. Plan → NSTEACS Pathway OR STEMI Mgt. Plan → STEMI Pathway

DO NOT WRITE IN THIS BINDING MARGIN

v6.00 - 02/2012
Mat. No.: 10206033
SW030a

CARDIAC CHEST PAIN RISK STRATIFICATION PATHWAY

Queensland Government

NSTEACS Management Plan

(Non-ST-Elevation Acute Coronary Syndrome, Non-ST-Elevation Myocardial Infarction)

For **Non-Interventional** Cardiac Facilities

Facility: .....

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

Clinical pathways never replace clinical judgement; Care outlined in this plan must be altered if it is not clinically appropriate for the individual patient

- This management plan must be used for patients that present with Non-ST-elevation Acute Coronary Syndrome (NSTEACS) following risk stratification in the Cardiac Chest Pain Risk Stratification Pathway
- **Assign an individual antithrombotic regimen. Management decisions must take into consideration the balance between ischaemic and bleeding risk for the individual patient** [1] (i.e. for patients with a high ischaemic risk and a low bleeding risk, assign an intensive antithrombotic therapy ***or*** for patients with a high risk of bleeding, assign a less intensive antithrombotic therapy)

Emergency presentation date: ..... time: .....

Onset of chest pain date: ..... time: .....

Initial Assessment / Management *(Tick as achieved. Record variance in patient record.)*	**Time**	**Initials**
☐ Referral completed for cardiology or medical review		
☐ Frequent observations temperature, pulse, resps (TPR), rhythm check, BP, heart sounds (HS), breath sounds (BS), SaO_2, circulation and neurological observations as per MO order, O_2 6L/min via HM if indicated (SaO_2 < 93% or evidence of shock)		
☐ Continuous cardiac monitoring, ECGs as per management plan		
☐ Check aspirin, 300mg administered as per MO orders, unless contraindicated or already given.		
☐ Clopidogrel 600mg administered unless contraindicated (or consider alternative)		

Cardiology Review / Management

- If TIMI **high risk**, refer for coronary angiography →

If...	**Transfer within...**
TIMI score of 6–7	24 hours
TIMI score of 3–5	48 hours
TIMI score of 2	72 hours
Positive EST	96 hours

- If patient has ongoing or recurrent ischaemia consider adding intravenous Tirofiban and refer for coronary angiography

TIMI *(Thrombolysis In Myocardial Infarction study group)* Risk Scores and 14-day Cardiac Event Rates

☐ Age greater than or equal to 65 years
☐ More than three coronary risk factors
☐ Prior angiographic coronary obstruction
☐ ST-segment deviation
☐ More than two angina events within 24 hours
☐ Use of aspirin within 7 days
☐ Elevated levels of cardiac biomarkers

Total *(score 1 point for each feature)*: .....

Time: ..... **Staff initials:** .....

TIMI score	**14-day event rate**
0/1	4.7%
2	8.3%
3	13.2%
4	19.9%
5	26.2%
6/7	40.9%

Source: Antman EM, Cohen M, Bernink PJ, et al. The TIMI risk score for unstable angina/non-ST elevation MI: a method for prognostication and therapeutic decision making. JAMA 2000; 284: 835-842.

Signature Log *(Every person documenting in this management plan **must** supply a sample of their initials and signature below)*

Initials	Signature	Print name	Role	Initials	Signature	Print name	Role

Patient with chest pain
ED Chest Pain Medical Assessment Tool

Acute Coronary Syndrome suspected/under investigation
Cardiac Chest Pain Risk Stratification Pathway
Intermediate Risk Chest Pain Clinical Pathway

Acute Coronary Syndrome diagnosed
NSTEACS Mgt. Plan
NSTEACS Pathway
OR
STEMI Mgt. Plan
STEMI Pathway

DO NOT WRITE IN THIS BINDING MARGIN

v5.00 - 02/2012 Mat. No.: 10217518 SW044a

NSTEACS MANAGEMENT PLAN NON-INTERVENTIONAL

Queensland Government

STEMI Management Plan

ST-Elevation Myocardial Infarction

For **Non-Interventional** Cardiac Facilities

Facility: .....

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐M ☐F ☐I

Clinical pathways never replace clinical judgement; Care outlined in this plan must be altered if it is not clinically appropriate for the individual patient

- This management plan must be used for patients that present with ST-elevation Acute Myocardial Infarction (STEMI) following risk stratification in the Cardiac Chest Pain Risk Stratification Pathway
- **Assign an individual antithrombotic regimen. Management decisions must take into consideration the balance between ischaemic and bleeding risk for the individual patient** [1]
  (i.e. for patients with a high ischaemic risk and a low bleeding risk, assign an intensive antithrombotic therapy ***or*** for patients with a high risk of bleeding, assign a less intensive antithrombotic therapy)

Emergency presentation date: ..... time: .....

Onset of chest pain date: ..... time: .....

Initial Assessment / Management Prior to Reperfusion *(Tick as achieved. Record variance in patient record.)*

a. **If symptom onset is less than 1 hour prior to presentation then consider transfer for immediate Percutaneous Coronary Intervention (PCI) within 60 minutes.**
b. **If symptom onset is 1–12 hours prior to presentation then consider transfer for immediate PCI within 90 minutes.**
c. **If patient cannot be transferred for PCI within the above timeframes, consider thrombolysis within 30 minutes.**

Reperfusion Guidelines

- Persistent ST-elevation ≥ 1mm in 2 contiguous limb leads (II, III, aVF / I, aVL)
- Persistent ST-elevation ≥ 2mm in 2 contiguous chest leads (V_1 - V_6) *Persistent ST-elevation < above may represent transmural ischaemia or pericarditis and should be considered for further investigation, including early angiography*
- New (or presumed new) left bundle branch block *Reperfusion therapy is not routinely recommended in late presentation patients who are asymptomatic and haemodynamically stable (ie. > 12 hrs after symptom onset).*

	Time	Initials
☐ ECG and right-sided ECG (V4R) if inferior MI on arrival, MO review within 10 mins		
☐ Referral completed for urgent Cardiology/Medicine review		
☐ Continuous cardiac monitoring, ECGs as per management plan		
☐ Frequent observations temperature, pulse, resps (TPR), rhythm check, BP, heart sounds (HS), breath sounds (BS), SaO_2, circulation and neurological observations as ordered, O_2 6L/min via HM if indicated (SaO_2 < 93% or evidence of shock)		
☐ Keep patient nil by mouth		
☐ Check aspirin, 300mg administered as per MO orders, unless contraindicated or already given.		
☐ Clopidogrel 300mg to 600mg administered unless contraindicated (or consider alternative)		

Cardiology Review / Management

If cathlab not available for PCI within timeframes, consider thrombolysis. See contraindications below.

	Time	Initials
☐ **Thrombolysis contraindicated, transfer arranged for immediate PCI** Omit subcut anticoagulation (consider IV anticoagulation)		
☐ **Patient suitable for thrombolysis:**		
☐ Informed consent obtained		
☐ Thrombolysis administered and IV Enoxaparin 30mg loading dose administered		
☐ *Thrombolysis successful* → ☐ Patient admitted to Cardiac Monitored Unit		
☐ Referred immediately—angiography recommended within 48 hours		
☐ *Thrombolysis unsuccessful at 90mins* ☐ Referred immediately for emergency rescue PCI		

Contraindications for Thrombolysis

Absolute:	Y	N
Active bleeding or bleeding diathesis (excluding menses)		
Significant closed head or facial trauma within 3 months		
Suspected aortic dissection		
Any prior intracranial haemorrhage		
Ischaemic stroke within 3 months		
Known structural cerebral vascular lesion		
Known malignant intracranial neoplasm		

Relative:	Y	N
Current use of anticoagulation		
Full dose GP IIb/IIIa inhibitors with fibrinolytic therapy, particularly in the elderly		
Noncompressible vascular punctures		
Traumatic or prolonged (> 10 min) CPR		
Ischaemic stroke > 3 months ago, dementia or known intracranial abnormality (not covered in 'absolute contraindications')		
Severe uncontrolled or chronic hypertension		
Recent major surgery (< 3 weeks)		
Recent internal bleeding (within 4 weeks)		
Advanced metastatic cancer		
Active peptic ulcer		
Pregnancy		

Management Post-Thrombolysis

- Frequent observations TPR, BP, HS, BS, SaO_2, circulation and neurological observations as per MO order
- ECGs must be taken at 90 mins, 6 hours and 12 hours
- Reduction (greater than 50%) in ST segments expected within 90 mins
- Continuous cardiac monitoring
- Relief of symptoms expected
- Haemodynamic stability achieved
- **If no resolution consider transfer for PCI**

Signature Log *(Every person documenting in this management plan **must** supply a sample of their initials and signature below)*

Initials	Signature	Print name	Role	Initials	Signature	Print name	Role

DO NOT WRITE IN THIS BINDING MARGIN

v7.00 - 03/2012 Mat. No.: 10217516 SW043a

STEMI MANAGEMENT PLAN NON-INTERVENTIONAL

Appendix F Data Abstraction Tool for Study Cohort

Queensland University of Technology
Brisbane Australia

PATIENT ID# ☐☐☐☐☐

Managing chest pain in rural emergency departments

DATA ABSTRACTION TOOL – STUDY COHORT

DEMOGRAPHIC INFORMATION

Health service	STA ☐	WRK ☐	MTI ☐
Data collector code			
Clinician code			
Date of presentation			
Sex	Female ☐	Male ……..☐	
Date of birth	D D M M Y Y Y Y ☐☐☐☐☐☐☐☐		

ATS CATEGORY (PLEASE CIRCLE)

1	**2**	**3**	**4**	**5**

ORGANISATIONAL INDICATORS

Arrival time	Time to R_x	LOS
H H : M M ☐☐☐☐	_____ minutes	_____ minutes

DISCHARGE DESTINATION

Medical	□1	Discharged	□6	Dead on arrival	□11
HDU/SSU	□2	Did not wait	□7	Died in ED	□12
Surgical	□3	LAMA	□8	Transfer to NH	□13
Palliative care	□4	Police	□9	Transferred	□14
Aged care	□5	Other	□10		

Queensland University of Technology
Brisbane Australia

DISCHARGE DIAGNOSIS (AS RECORDED IN EDIS)

.....

UNPLANNED REPRESENTATION WITHIN SEVEN DAYS

1. Did the patient represent to the ED within seven days of initial presentation?

   No ..... ☐1 **Data collection is complete**

   Yes ..... ☐2 go to Q2

2. Was the presentation for chest pain?

   No ..... ☐1 **Data collection is complete**

   Yes ..... ☐2 go to Q3

3. Was there a major adverse cardiac event (MACE)?

   No ..... ☐1 **Data collection is complete**

   Yes ..... ☐2 go to Q4

4. What was the MACE?

   Death ..... ☐1

   Cardiac arrest ..... ☐2

   AMI (STEMI or NSTEMI) ..... ☐3

   Arrhythmia ..... ☐4

   Cardiogenic shock ..... ☐5

   Other ..... ☐6

IF SUSPECTED OR CONFIRMED ACUTE CORONARY SYNDROME (EG. POSSIBLE CARDIAC CHEST PAIN, ANGINA, MYOCARDIAL INFACTION) PLEASE COMPLETE DATA ABSTRACTION TOOL FOR NESTED COHORT.

OTHERWISE, DATA COLLECTION IS COMPLETE

Appendix G Data Abstraction Tool for Nested Cohort

Queensland University of Technology
Brisbane Australia

PATIENT ID# ☐☐☐☐☐

Managing chest pain in rural emergency departments

DATA ABSTRACTION TOOL – NESTED COHORT

TIME OF ARRIVAL: H H: M M ☐☐☐☐

TIME REVIEWED BY CLINICIAN: H H:M M ☐☐☐☐

RISK STRATIFICATION

High risk features ☐1	**Intermediate risk features** ☐2
Repetitive or ongoing CP (>10mins) ☐1	Resolved CP within past 48/24 at rest, or repetitive or prolonged (>10 mins) ☐1
Elevated TnI ☐2	Age > 65 yrs ☐2
ECG changes ☐3	Diabetes ☐3
LVEF <0.40 ☐4	IHD (prior MI with LVEF >0.40, or known coronary lesion more than 50% stenosed) ☐4
Haemodynamic compromise ☐5	Two or more risk factors: HT, FH, smoker, hyperlipidaemia ☐5
Sustained VT ☐6	Prior regular aspirin use ☐6
Syncope ☐7	CKD – GFR <60mL/min ☐7
Prior PCI within 6/12 or prior CABG ☐8	
Low risk features ☐3	
No intermediate or high risk features	

ECG

Performed on arrival	No ☐1	Yes ☐2
Reviewed within 10 mins	No ☐1	Yes ☐2

PLEASE ATTACH COPY OF INITIAL ECG

Queensland University of Technology
Brisbane Australia

TROPONIN

On arrival	No ☐1	Yes ☐2
		Level:

Repeat	Time:	Level:

MEDICATIONS PRESCRIBED IN THE ED

Aspirin	No ☐1	Yes ☐2
	Contraindicated ☐3	Dose
	Already given ☐4	

Clopidigrel	No ☐1	Yes ☐2
	Contraindicated ☐3	Dose

Enoxaparin	No ☐1	Yes ☐2
	Contraindicated ☐3	Dose

Thromobolysis	No ☐1	Yes ☐2
	Contraindicated ☐3	Which?

REFERRAL FOR PCI ATTENDED IN ED

No ..... ☐1

Yes ..... ☐2

CHEST XRAY

No ..... ☐1

Yes ..... ☐2

Appendix H Research assistants protocol

Housework

1. Introduce yourself to the triage nurse and clinicians in the Emergency Department and remind them of the MaP-RED study.
2. Ask the triage nurse or clinicians to contact you if they have a patient who has presented with chest pain to the ED. **Provide a contact number for the day.**
3. Remind clinicians of the Queensland Health Chest Pain Stratification Tool and request they use (if possible)
4. Check that you have all the paperwork required in the MaP-RED box which is located in the triage room.
5. Ensure that you have a pen for the consent clipboard.
6. Check that MaP-RED signs are in place near computers in the ED.

Clinical Research Assistants

1. Present to the ED as soon as possible after being contacted regarding a patient presentation.
2. Supply the appropriate Patient Information & Consent Form (PICF) to the patient or the legally authorised representative. Explain that they are invited to participate in the study.
3. Commence the Site Screen and Enrollment Log. We need to keep count of how many patients were screened, how many refused to participate or were found to be ineligible. Collect minimal demographic details for every patient.
4. Answer any questions from the patient (or legally authorised representative).
5. Collect the signed consent form. Place a Patient ID label on it.
6. Place a Patient ID label on Patient Questionnaire and either a Yellow Dot for ENP care or Blue Dot for Standard Care.
7. Administer Patient Questionnaire. The RA can answer questions, address concerns about the questionnaire, and ensure the questionnaire is correctly and completely filled out. The RA is required to retrieve the form upon completion and check for completeness before the participant leaves.
8. Collect completed questionnaire and remind participants that they will receive another questionnaire for completion in the mail in 30-days.
9. Photocopy consent form and return a copy to the patient.
10. Place the completed questionnaire (with consent form stapled to the front) in the red folder in the MaP-RED box.

Outcome Research Assistants

1. Check the red MaP-RED folder each day.
2. Commence the Data Abstraction Tool - Study Cohort for every patient.
3. Complete the Data Abstraction Tool – Nested Cohort for patients with suspected or confirmed acute coronary syndrome. Copy the ECG used for diagnosis and attach to form.
4. Complete the Data Abstraction Tool – Study Cohort. Check EDIS for unplanned representation within the following seven days.
5. Collate the PICF, Patient Questionnaire, Data Abstraction Tools and ECG (if required) and return to the Principal Investigator, Tina Roche.

Contact Details for Principal Investigator
Tina Roche
Emergency Nurse Practitioner, Stanthorpe Health Services
PO Box 273, Stanthorpe Queensland 4380
Email: tina.roche@hdr.qut.edu.au
Phone (anytime): 0400 835 229

Appendix I HREC approval

Queensland Government

Department of Health

28 August 2014

Enquiries to: Health & Medical Research
Human Research Ethics Committee
Phone: 07 3328 9866
HREC Ref: HREC/14/QHC/30
E-mail: HMR_REG@health.qld.gov.au

Mrs Tina Roche
68 Greenup Street
STANTHORPE QLD 4380

Dear Mrs Roche

HREC Reference number: HREC/14/QHC/30
Project Title: A longitudinal nested cohort study to evaluate the effectiveness of emergency nurse practitioner service for rural patients presenting with chest pain.

Thank you for submitting the above research protocol to the Queensland Health Central Office Human Research Ethics Committee for ethical and scientific review. This protocol was first considered by the Human Research Ethics Committee (HREC) at the meeting held on 21 July 2014.

I am pleased to advise that the HREC has granted approval of this research protocol.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the District CEO or Delegate of that site has been obtained.

A copy of this approval must be submitted to the District Research Governance Office(r)/Delegate of the relevant institutions with a completed Site Specific Assessment (SSA) Form for authorisation from the CEO or Delegate to conduct this research within Queensland Health

The documents reviewed and approved include:

Document	Version	Date
Application		
PICF (Adult)	1	June 2014
PICF (Person Responsible)	1	June 2014
Data tool (Nested Cohort)	1	June 2014
Data tool (Study Cohort)	1	June 2014
Response to request for further information		26 August 2014
Protocol	2	August 2014
PICF (Emergency NP)	2	August 2014
Questionnaire (Occasion of service)	2	August 2014
Questionnaire (Follow-up)	2	August 2014

Please note the following conditions of approval:

1. The Coordinating Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that

might affect continued ethical acceptability of the protocol. Serious Adverse Events must be notified to the HREC as soon as possible. In addition the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Coordinating Principal Investigator, including duration of treatment and outcome of the event.

2. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review. Major amendments should be reflected in a revised online NEAF (accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents, with *tracked changes*, must also be submitted to the HREC office as per standard HREC SOP. (Further advice on submitting amendments is available at http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf
3. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
4. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
5. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically (track changes) and in hard copy (final clean copy) to the Research Ethics Manager. These should include a cover letter from the Coordinating Principal Investigator or Study Co-ordinator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
6. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
7. The Coordinating Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.

This HREC approval is valid for 3 years from the date of this letter.

8. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.
9. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

Should you have any queries about the HREC's consideration of your protocol please contact the Ethics Secretariat on 07 3288 9866

Please note that the Queensland Health Central Office HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia*

Office	Postal	Phone	Fax
Department of Health Level 1 15 Butterfield Street Herston QLD 4006	HMR – Level 1 PO Box 2368 Fortitude Valley BC QLD 4006	61 7 3328 9866	61 7 3328 9115

Australian Code for the Responsible Conduct of Research (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition with specialty and affiliation with the Hospital (Attachment I).

The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the following website:
http://www.health.qld.gov.au/ohmr/html/regu/hrec_contacts.asp

*Once authorisation to conduct the research has been granted, please complete the Commencement Form (*Attachment II*) and return to the Queensland Health Central Office Human Research Ethics Committee or email to HMR_REG@health.qld.gov.au .*

The Queensland Health Central Office HREC wishes you every success in your research.

Yours sincerely,

Professor Mervyn Eadie
Chair
Queensland Health Central Office
Human Research Ethics Committee (EC00334)

Appendix 1

Sites
Mt Isa Hospital and Health Services
Stanthorpe Health Services
Warwick Health Services

Office
Department of Health
Level 1
15 Butterfield Street
Herston QLD 4006

Postal
HMR – Level 1
PO Box 2368
Fortitude Valley BC QLD 4006

Phone
61 7 3328 9866

Fax
61 7 3328 9115

Queensland
Government

Medical Services

Darling Downs Hospital and Health Service

Enquiries to: Wendy Friend
Telephone: (61 7) 4616 6696
Facsimile: (61 7) 4616 5099
Our Ref: SSA/15/QTDD/23

Mrs Tina Roche
C/O Professor Glenn Gardner
School of Nursing
Institute of Health and Biomedical Innovation
KELVIN GROVE QLD 4059

Dear Mrs Roche

HREC reference number: HREC/15/QTDD/18
SSA reference number: SSA/15/QTDD/23
Project title: A longitudinal nested cohort study to evaluate the effectiveness of emergency nurse practitioner service for rural patients presenting with chest pain.

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to take place at the following site:

- Kingaroy Hospital

The following conditions apply to this research proposal. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval.

1. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project are to be submitted to the HREC for review. A copy of the HREC approval/rejection letter must be submitted to the RGO;
2. Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project, are to be submitted to the research governance officer;
3. Proposed amendments to the research protocol or conduct of the research which may affect both the ongoing ethical acceptability of the project and the site acceptability of the project are to be submitted firstly to the HREC for review and then to the research governance officer after a HREC decision is made.

Yours sincerely

Dr Peter Bristow FRACP FCICM FRACMA GCM GAICD
Chief Executive
Darling Downs Hospital & Health Service
11/4/15

Medical Services
Pechey Street Toowoomba
PMB 2 Toowoomba
Queensland 4350 Australia
Telephone +61 7 4616 6151
Facsimile +61 7 4616 5099
www.health.qld.gov.au/darlingdowns

ABN 64 109 516 141

Queensland Government

Medical Services

Darling Downs Hospital and Health Service

Enquiries to: Wendy Friend
Telephone: (61 7) 4616 6696
Facsimile: (61 7) 4616 5099
Our Ref: HREC/15/QTDD/18

Mrs Tina E Roche
68 Greenup Street
STANTHORPE QLD 4380

Dear Mrs Roche

HREC Reference number: HREC/15/QTDD/18
Project title: A longitudinal nested cohort study to evaluate the effectiveness of emergency nurse practitioner service for rural patients presenting with chest pain.
Amendment number: HREC/14/QHC/30/AM01
Amendment Date: 26 February 2015

The above amendment was reviewed by the Chair of the Darling Downs Hospital and Health Service Human Research Ethics Committee.

I am pleased to advise that the amended documents reviewed and approved at the meeting were:

Document	Version	Date
Notification of amendment: Addition of Kingaroy Hospital as a participating site.	Email	26 Feb 2015

The Darling Downs Hospital and Health Services HREC is constituted and operates in accordance with the National Health and Medical Research Council's *"National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *"CPMP/ICH Note for Guidance on Good Clinical Practice"*.

A copy of this letter must be forwarded to the Research Governance Officer.

It should be noted that all requirements of the original approval still apply.

Yours sincerely

HSChong

Dr Hwee Sin Chong MBChB MHM FRACMA
Chair
Darling Downs Hospital & Health Service
Human Research Ethics Committee

25/3/15

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Pechey Street Toowoomba
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www.health.qld.gov.au/darlingdowns

ABN 64 109 516 141

Appendix J QUT ethics approval

Thursday, 6 November 2014 11:20:57 am Australian Eastern Standard Time

Subject: Ethics Application Approval-- 1400000709
Date: Wednesday, 15 October 2014 2:19:58 pm Australian Eastern Standard Time
From: Research Ethics
To: Glenn Gardner, Peter Lewis, Tina Roche
CC: Janette Lamb

Dear Prof Glenn Gardner and Mrs Tina Roche

Project Title: A longitudinal nested cohort study to evaluate the effectiveness of emergency nurse practitioner service for rural patients presenting with chest pain

Ethics category: Human - Administrative Review
QUT approval number: 1400000709 (As per Queensland Health - Central Office Human Research Ethics Committee, Approval number: HREC/14/QHC/030)
QUT clearance until: 28/08/2017

We are pleased to advise that your application has been reviewed and administratively approved by the Chair, University Human Research Ethics Committee (UHREC) based on the approval gained from the responsible HREC. We note this HREC has awarded the project ethical clearance until 28/08/2017.

CONDITIONS OF APPROVAL
Please ensure you and all other team members read through and understand all UHREC conditions of approval prior to commencing any data collection:
- Standard: Please see attached or www.research.qut.edu.au/ethics/humans/stdconditions.jsp
- Specific: None apply

Administrative review decisions are subject to ratification at the next available UHREC meeting. You will only be contacted again in relation to this matter if UHREC raises additional questions or concerns.

Projects approved through an external organisation may be subject to that organisation's review arrangements. Researchers must immediately notify the QUT Research Ethics Unit if their project is selected for investigation / review by an external organisation.

VARIATIONS
All variations must first be approved by the responsible HREC before submission to QUT for ratification. Once approval has been obtained please submit this to QUT using our online variation form:
http://www.orei.qut.edu.au/human/var/

MONITORING
Please ensure you also provide QUT with a copy of each adverse event report and progress report submitted to the responsible HREC.

Please don't hesitate to contact us if you have any queries.

We wish you all the best with your research.

Kind regards

Janette Lamb on behalf of Chair UHREC

Appendix K ANZCTR confirmation

Thursday, 23 June 2016 at 12:08:42 PM Australian Eastern Standard Time

Subject: Your ACTRN (registration number): ACTRN12616000823471
Date: Thursday, 23 June 2016 at 12:07:13 PM Australian Eastern Standard Time
From: info@actr.org.au
To: Tina Roche

Dear Tina Roche,

Re: Effectiveness of an emergency nurse practitioner service for adults presenting to rural hospitals with chest pain

Thank you for submitting the above trial for inclusion in the Australian New Zealand Clinical Trials Registry (ANZCTR).

Your trial has now been successfully registered and allocated the ACTRN: ACTRN12616000823471

Web address of your trial: http://www.ANZCTR.org.au/ACTRN12616000823471.aspx
Date submitted: 15/06/2016 10:26:37 AM
Date registered: 23/06/2016 12:07:09 PM
Registered by: Tina Roche

****Please note that as your trial was registered after the first participant was enrolled, it does not fulfil the criteria for prospective registration and will therefore be marked as being Retrospectively Registered on our website.****

If you have already obtained Ethics approval for your trial, could you please send the ANZCTR a copy of at least one Ethics Committee approval letter? A copy of the letter can be sent to info@actr.org.au (by email) OR (61 2) 9565 1863, attention to ANZCTR (by fax).

Please be reminded that the quality and accuracy of the trial information submitted for registration is the responsibility of the trial's Primary Sponsor or their representative (the Registrant).
The ANZCTR allows you to update trial data, but please note that the original data lodged at the time of trial registration and the tracked history of any changes made will remain publicly available.

The ANZCTR is recognised as an ICMJE acceptable registry (http://www.icmje.org/faq.pdf) and a Primary Registry in the WHO registry network (http://www.who.int/ictrp/network/primary/en/index.html).

If you have any enquiries please send a message to info@actr.org.au or telephone +61 2 9562 5333.

Kind regards,
ANZCTR Staff
T: +61 2 9562 5333
F: +61 2 9565 1863
E: info@actr.org.au
W: www.ANZCTR.org.au

Appendix L STROBE Statement

	Item No	Recommendation	Page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	140
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	140
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	141
Objectives	3	State specific objectives, including any prespecified hypotheses	143-144
Methods			
Study design	4	Present key elements of study design early in the paper	144
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	144
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	144
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	145
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	145-146
Bias	9	Describe any efforts to address potential sources of bias	162
Study size	10	Explain how the study size was arrived at	147
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	147
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	147-148
		(*b*) Describe any methods used to examine subgroups and interactions	147-148
		(*c*) Explain how missing data were addressed	138
		(*d*) If applicable, explain how loss to follow-up was addressed	N/A
		(*e*) Describe any sensitivity analyses	147-148
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	148
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	148-151
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) Summarise follow-up time (eg, average and total	145

		amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	151-156
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	151-156
		(*b*) Report category boundaries when continuous variables were categorized	151-156
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	151-156
Discussion			
Key results	18	Summarise key results with reference to study objectives	156-161
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	156-161
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	156-161
Generalisability	21	Discuss the generalisability (external validity) of the study results	161-162
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	163

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

Appendix M Evidence of manuscript acceptance

From: ajr.eo@wiley.com
Date: 10 July 2014 12:01:09 pm AEST
To: tinaroche@y7mail.com
Subject: Australian Journal of Rural Health - Decision on Manuscript ID AJRH-02-2014-0032.R1
09-Jul-2014

Dear Mrs. Roche:

It is a pleasure to accept your manuscript entitled "A retrospective observational study of patients who present to Australian rural emergency departments with undifferentiated chest pain." in its current form for publication in the Australian Journal of Rural Health.

Once your manuscript has been allocated to an issue, you will receive final proofs via email as an Acrobat PDF file. This proof will show the final revised text as it will appear in the printed journal. At this stage tables and figures will be included and this is your final opportunity to pick up essential corrections only. Further instructions will be sent with the proof.

If there is a possibility that you will be away, please arrange for a colleague to access your email to retrieve the proofs and check them on your behalf.

Thank you for your fine contribution. On behalf of the Editors of the Australian Journal of Rural Health, we look forward to your continued contributions to the Journal.

Yours sincerely

A/Prof. Christopher Roberts
Associate Editor
Australian Journal of Rural Health

Subject: BMJ Open - Decision on Manuscript ID bmjopen-2014-006997.R2
Date: Monday, 12 January 2015 at 10:17:22 PM Australian Eastern Standard Time
From: editorial.bmjopen@bmj.com (sent by onbehalfof+editorial.bmjopen+bmj.com@manuscriptcentral.com <onbehalfof+editorial.bmjopen+bmj.com@manuscriptcentral.com>)
To: Tina Roche
CC: Tina Roche, Glenn Gardner, Peter Lewis

12-Jan-2015

Dear Mrs. Roche:

It is a pleasure to inform you that your manuscript "Effectiveness of an emergency nurse practitioner service for adults presenting to rural hospitals with chest pain: Protocol for a multi centre, longitudinal nested cohort study" has been accepted for publication in BMJ Open.

To enable all articles published in BMJ Open to be fully open access, an article-processing charge (APC) is levied. This charge supports the journal's peer review process, production costs (typesetting, copy editing, etc.), and the costs of maintaining the content online and marketing it to readers.

Therefore, your payment of £1000 (excluding any applicable VAT) is now due.

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Please note, a number of institutions have taken out Open Access Memberships with BMJ, which either covers the cost of open access publishing for authors at participating institutes, or allows authors to receive a discount on the article-processing charge. Please visit our open access page to see a full list of participating institutions, find out if you are eligible and how to obtain your discount code - http://journals.bmj.com/site/authors/openaccess.xhtml#open-access-institutional-memberships.

Once your article is published online you will be able to keep track of usage. Each article published in BMJ Open has individual usage statistics which are updated daily and can be accessed from the Article Usage Statistics link in the Services section of the right hand column on each page of the article. In this column you can also sign up to be alerted about any e-letter responses to your article.

Thank you for your contribution, and we hope that you will continue to submit to the journal in future.

Sincerely,
Richard Sands, managing editor
Editorial Office, BMJ Open
editorial.bmjopen@bmj.com
http://bmjopen.bmj.com

Subject: Emergency Medicine Australasia - Decision on Manuscript ID EMA-2015-327.R2
Date: Thursday, 12 May 2016 at 10:55:50 AM Australian Eastern Standard Time
From: ema.eo@wiley.com (sent by onbehalfof+ema.eo+wiley.com@manuscriptcentral.com <onbehalfof+ema.eo+wiley.com@manuscriptcentral.com>)
To: Tina Roche

11-May-2016

Dear Mrs. Roche:

It is a pleasure to accept your revised manuscript entitled "Diagnostic accuracy of risk stratification tools for patients with chest pain in the rural emergency department: a systematic review" in its current form for publication in Emergency Medicine Australasia. The comments of the Section Editor and the reviewers are attached below.

First Look NEW: Please note although the manuscript is accepted the files will now be checked to ensure that everything is ready for publication, and you may be contacted if final versions of files for publication are required.

Thank you for your fine contribution. On behalf of the Editors of Emergency Medicine Australasia, we look forward to your continued contributions to the Journal.

Your article cannot be published until you have signed the appropriate license agreement. Within the next few days you will receive an email from the Wiley Author Services system which will ask you to log in and will present you with the appropriate licence for completion.

Sincerely,
Prof. Geoff Hughes
Editor-in-Chief
Emergency Medicine Australasia

Section Editor: Yeoh, Michael
Comments to the Author:
(There are no comments.)

Reviewers' Comments to Author:

Subject: Australian Health Review - Manuscript AH16152
Date: Tuesday, 12 July 2016 at 4:30:30 PM Australian Eastern Standard Time
From: Australian Health Review
To: Tina Roche, Glenn Gardner, Leanne Jack

12-Jul-2016

Dear Mrs Roche

Your manuscript entitled 'Perils and pitfalls in conducting rural health services research: a biographical case study' has been successfully submitted online and will be given full consideration for publication in Australian Health Review.

Your manuscript ID is AH16152. Please mention this manuscript ID in all future correspondence or when calling the office with questions.

If there are any changes in your street address or email address, please log in to ScholarOne Manuscripts at https://mc.manuscriptcentral.com/csiro-ah and edit your details as appropriate. You can also view the status of your manuscript at any time by checking your Author Centre after logging in.

Thank you for submitting your manuscript to Australian Health Review.

Sincerely,

Editorial Office, Australian Health Review

View Letter

Close

Date: 08 Jul 2016
To: "Tina Roche" tina.roche@hdr.qut.edu.au
From: "BMC Health Services Research Editorial Office" bmchealthservres@biomedcentral.com
Subject: Confirmation of your submission to BMC Health Services Research - BHSR-D-16-00926

BHSR-D-16-00926
The effectiveness of emergency nurse practitioner service in the management of patients presenting to rural hospitals with chest pain: a multisite prospective longitudinal nested cohort study.
Tina Roche, MNSc; Glenn E Gardner; Leanne Jack
BMC Health Services Research

Dear Mrs Roche,

Thank you for submitting your manuscript 'The effectiveness of emergency nurse practitioner service in the management of patients presenting to rural hospitals with chest pain: a multisite prospective longitudinal nested cohort study.' to BMC Health Services Research.

The submission id is: BHSR-D-16-00926
Please refer to this number in any future correspondence.

During the review process, you can keep track of the status of your manuscript by accessing the following website:

http://bhsr.edmgr.com/

If you have forgotten your username or password please use the "Send Login Details" link to get your login information. For security reasons, your password will be reset.

Best wishes,

Editorial Office
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